UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff, *ex rel.* GEORGE MARKELSON, as Executor of the Estate of STEPHEN MARKELSON, Deceased, and PETER NADLER and LORRAINE WATERS, Plaintiffs-Relators, v. DAVID B. SAMADI, M.D., DAVID B. SAMADI, M.D., P.C., LENOX HILL HOSPITAL and NORTHWELL HEALTH, INC., Defendants.	**Case No. 17-cv-7986** **AMENDED COMPLAINT** **Filed Under Seal** pursuant to the False Claims Act, 31 U.S.C. § 3730 (b)(2) **JURY TRIAL DEMANDED**

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I. INTRODUCTION

1. Plaintiff-Relators (also "Relators") George Markelson, as Executor of the Estate of Stephen Markelson, Deceased, Peter Nadler, and Lorraine Waters bring this *qui tam* case on behalf of the United States of America, against David B. Samadi, M.D. ("Dr. Samadi"), David B. Samadi, M.D., P.C., Lenox Hill Hospital ("Lenox Hill"), and Northwell Health, Inc. ("Northwell") (collectively "Defendants"), pursuant to the federal False Claims Act, 31 U.S.C. § 3729 *et seq.* seeking damages resulting from the submission of thousands of false claims to government payers, including, but not limited to, Medicare, TRICARE and other government-funded health insurance plans for urological procedures and surgeries that did not conform in material respects to Medicare.

2. Lenox Hill's urology department, which trains residents (physicians who have recently graduated from medical school and are receiving advanced training), is considered a teaching hospital and, as such, is obligated to follow specific Medicare rules when billing for services provided by its residents. The hospital must also comply with other Medicare rules governing, *inter alia*, treatment, informed consent, and record keeping in order, as well as abide by the Stark law and Anti-Kickback Statute to be reimbursed by government payers. Submitting claims for reimbursement to government payers without conforming to such statutes and regulations results in liability under the False Claims Act.

3. Defendants have engaged in a scheme – since at least 2013 -- to systematically submit false claims to government payers for services that do not conform to statutes and regulations in material respects, including claims for: (1) "simultaneous" or "concurrent" urologic surgeries conducted by Dr. Samadi and residents in violation of Medicare rules; (2) medically unnecessary general anesthesia services; (3) medical treatment undertaken without proper informed consents from patients; (4) medical treatment documented with false and/or

misleading records; (5) "upcoded" robotic urologic surgeries performed by Dr. Samadi involving "lymph node sampling" billed as "peripheral lymph node dissections;" (6) Stark Law and Anti-Kickback Statute violations related to compensation paid to Dr. Samadi; and (7) violation of rules that must be followed in order to receive funds from the Accreditation Council for Graduate Medical Education (hereafter "ACGME") to pay Lenox Hill's residents and fellows.

4. Relators have first-hand knowledge of both Defendants' failure to follow these rules and the submission of false claims to Medicare for payment. Both Relator Peter Nadler and the late Stephen Markelson were patients of Dr. Samadi whose urologic surgeries were performed by residents not properly supervised by Dr. Samadi and, as a result, they received suboptimal care at Lenox Hill, which led to further serious complications and additional treatments that could have been avoided had Medicare rules been followed.
5. Moreover, Dr. Samadi guaranteed to Relators Markelson and Nadler that he would personally perform their surgeries and Lenox Hill's written informed consent forms specifically identified Dr. Samadi as the surgeon performing the surgery.
6. Had Mr. Markelson and Mr. Nadler known that Dr. Samadi would not personally perform their surgeries, they would not have consented to surgery. Nothing in the consent forms indicated the following: (1) that an unsupervised resident would be performing their surgeries; (2) the identity and experience level of the unsupervised resident; and (3) that Dr. Samadi would be operating on other patients in other operating rooms while relators were undergoing surgery.
7. Thus, the Relators' surgeries violated the required informed consent and their surgeries constituted non-consensual treatment.

8. Defendants' own urologic surgery databases (encompassing the period 2004 to 2016), Operating Room ("OR") schedules, and anesthesia records, among other documents, records, and databases, corroborate the unlawful billing scheme.[1]

A. CONCURRENT SURGERY PRACTICE

9. Relators' records show that Dr. Samadi scheduled nearly 1,000 urologic surgeries concurrently – meaning that the procedures did not merely overlap on their margins, but were instead scheduled at or about the same time, making it impossible for him to assure that he could be physically present during key and critical parts and/or the "entire viewing" of an endoscopic / laparoscopic surgery, as required by Medicare.

10. A teaching physician may only leave the first surgery when the key or critical elements *are completed*.[2] Residents or fellows may finish the non-critical parts.[3] Surgeries in compliance with this rule are often called overlapping surgeries. Even after the teaching or attending surgeon has left, however, Medicare rules require him/her to have arranged for another qualified surgeon to be immediately available to assist the resident in the first case should the need arise.[4]

11. CMS[5] will not pay for surgeries where the key or critical elements of each surgery take place at the same time (generally called concurrent surgeries). Nor should patients be subjected to treatment by unsupervised residents who come to the teaching hospital to be trained to perform specialized surgeries, such as those at issue in this case.

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[1] These documents were submitted by the Relators to the United States of America and are incorporated by reference in the allegations of this Amended Complaint. As such, these documents form some of the bases for factual allegations in the Amended Complaint.

[2] *See* CMS 2018 Claims Manual at 100.1.2 (Surgical Procedures) A (available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf:, (last viewed on March 5, 2019))

[3] CMS Manual System, Pub 100-04 Medicare Claims Processing (Transmittal 2303) (Sept. 14, 2011) (hereafter "CMS 2011 Claims Manual") at 100.1.2 (Surgical Procedures) A.

[4] *Id.*

[5] Centers for Medicare & Medicaid Services ("CMS").

12. Moreover, the services performed by interns and residents are already reimbursed under Medicare Part A. When CMS makes an additional payment for the same services under a physician fee schedule and a supervising physician is not present as required, it is paying for a service that was simply never provided.

13. Dr. Samadi failed to follow these rules. Instead, he devised a scheme where he intentionally left second- and third-year residents[6] unsupervised (and without another qualified surgeon available to assist if needed) to conduct surgeries in O.R. 21 at Lenox Hill, while he simultaneously or concurrently performed robotic assisted laparoscopic prostatectomy surgeries ("RALPs")[7] in O.R. 25 at Lenox Hill.

B. VIOLATIONS OF STARK ACT AND THE ANTI-KICKBACK STATUTE

14. Lenox Hill and its parent Northwell knew about and condoned Dr. Samadi's concurrent surgery practice – notwithstanding its potential to harm patients – because it was extremely profitable. Indeed, Lenox Hill and Northwell hired Dr. Samadi for the purpose of enhancing the health systems' expansion and competitiveness.[8] His employment contract includes bonus and incentive clauses based on surgical volume and revenue to the hospital.[9] By 2016, Dr. Samadi's compensation had increased by $2.9 million under this contract.[10]

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[6] A resident is a medical school graduate engaged in in-depth training in a medical specialty, which may last from 3-5 years depending upon the specialty. Residents are to be supervised by teaching physicians, also called "attending physicians," who approve their decision-making. According to the ACGME, a "resident" is "[a]ny physician in an accredited graduate medical education program, including interns, residents, and fellows." See AGME Glossary of Terms (Glossary of Terms, July 1, 2013);https://medicine.umich.edu/sites/default/files/content/downloads/ab_ACGMEglossary.pdf

[7] "RALP" is the acronym for "robotic assisted laparoscopic prostatectomy" and is used interchangeably with that term in this Amended Complaint.

[8] See, "New York's $9.6 million man and other top health earners," G. Schifman, Crain's NY Business, April 13, 2016.

[9] *Id.*

[10] *Id.*

15. Doctor Samadi's compensation far exceeded fair market value for his services and were based on the volume and revenue generation. This compensation was particularly remarkable considering that Dr. Samadi materially neglected one of his purported services: ensuring that the program for residents complied with ACGME requirements necessary for the accreditation that is a predicate to federal funding of Graduate Medical Education.

16. A Northwell executive referred to Dr. Samadi as "prolific in [his] field" and acknowledged that his compensation increase was "tied to [his] responsibility and [his] importance to the organization" with compensation that is "competitive but justifiable in terms of [his] value to the system."[11]

C. Medically Unnecessary Anesthesia and Invalid Informed Consent

17. In order to conceal their concurrent surgery billing scheme, Dr. Samadi and other physicians employed by Lenox Hill ordered and placed *all* of Dr. Samadi's patients under anesthesia – even those who did not require it – so that patients would not learn that Dr. Samadi was not present for their surgery during key and critical parts and/or for the entire viewing of endoscopic/laparoscopic surgeries.

18. Nothing in Defendants' patient consent forms advised patients that Dr. Samadi would not be present during the entire surgery and Dr. Samadi falsely advised patients that he would conduct their surgeries. Patients undergoing the urological surgeries in O.R. 21 for TURPs[12]

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[11] *Id.*

[12] A TURP is a Transurethral Resection of the Prostate, which entails "visualizing the prostrate through the urethra," using a resectoscope and "removing tissue by electrocautery or sharp dissection." A resectoscope is "a surgical instrument that is passed along the male urethra to allow a view of the inside of the bladder and of an enlarged prostate gland. The resectoscope incorporates an electrically heated wire loop used to cut away redundant prostate tissue so as to allow the free outflow of urine." See, https://medical-dictionary.thefreedictionary.com/resectoscope

(or other non-robotic surgeries) were falsely led to believe that Dr. Samadi would be performing the planned surgery on them.[13]

19. Aside from the remarkable ethical implications resulting from Defendants' efforts to conceal Dr. Samadi's scheme, using general anesthesia for the surgeries performed by residents in O.R. 21 (such as the TURP operation) is medically unnecessary and is not supported by standard urology practice; the surgical procedures are customarily and safely performed under spinal or epidural anesthesia with sedation.

20. Moreover, to the extent patients receiving RALPs in O.R. 25 were left under anesthesia while Dr. Samadi was in O.R. 21 or other locations outside O.R. 25, they were exposed to prolonged anesthesia, which was likewise medically unnecessary.

21. Billing for unnecessary medical treatment *also* violates material rules of the Medicare statutes that, without exception, forbid payment "for any expenses incurred for items or services which ... are not *reasonable and necessary* for the diagnosis or treatment of illness or injury to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A) (Emphasis Added).

22. The Defendants regularly billed for unnecessary anesthesia services provided in these unsupervised surgeries, knowing that the requests for payment were false claims pursuant to the False Claims Act.

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[13] In *Universal Health Servs. v. United States et. al. ex rel. Escobar*, 136 S. Ct. 1989, 2000 (2015), Justice Thomas reiterated "the rule that half-truths – representations that state the truth only so far as it goes, while omitting critical qualifying information – can be actionable misrepresentations." Further, the opinion notes that in "tort law, for example, 'if the defendant does speak, he must disclose enough to prevent his words from being misleading.'" *Id.* at 2000 n.3 (internal quotation marks omitted).

23. Defendants also submitted false claims for surgeries, anesthesia services and related medical treatment that were provided without proper informed consent. Contrary to these fraudulent representations, approximately one thousand or more of Dr. Samadi's patients underwent surgery by unsupervised second- and third-year urology residents and were placed under general anesthesia without a proper informed consent.

24. The hospital defendants were on notice of the fraudulent informed consent forms and other assurances made by Dr. Samadi. Notwithstanding, Defendants billed government payers for claims that were tainted by violations of Medicare rules pertaining to informed consent and unnecessary services in contravention of the False Claims Act.[14]

D. Falsified Patient Records

25. Defendants' bills to government health care payers were also false because the medical records (*e.g.*, operative reports, anesthesia records, operative case records, etc.) falsely indicated that Dr. Samadi had either performed the surgery, was present for "the critical or key portions of the surgery," and/or was present for the "entire viewing" portion of the endoscopic / laparoscopic surgery for the operations in O.R. 21 that had been performed by the unsupervised residents. Medicare rules require accurate record keeping to support submissions for medical services and payment thereof; therefore, false medical records are material violations of the rules that result in liability under the False Claims Act.

E. Billing for Procedures That Were Never Performed

26. Defendants billed government payers, including Medicare for "bilateral peripheral lymph node dissections" that were never performed and performed "lymph node sampling" that served no medical purpose (*i.e.* it was not "medically necessary"). The Defendants prepared informed

[14] See, 42 C.F.R. 415.172(b).

consents and operative reports falsely asserting that they would perform and did perform "bilateral peripheral lymph node dissections" when in fact Dr. Samadi did not resect the entire lymph node package on either side of the pelvis. Instead, Dr. Samadi only resected one lymph node from the left and right. This procedure amounts to what is known as "lymph node sampling;" however, it serves no medical purpose in the staging of prostate cancer and was done as a time saving measure by Dr. Samadi so he could perform more RALPs in the course of an operating day.

27. In sum, Defendants billed government payers for claims that were tainted by the foregoing violations of Medicare rules, rendering the claims "false" in contravention of the False Claims Act.[15]

28. In addition, Defendants' claims for reimbursement were tainted remuneration provided to Dr. Samadi proscribed under the Stark Act, 42 U.S.C. § 1395nn, and the Anti-Kickback Statute,42 U.S.C. §1320a-7b(b).

29. Knowingly submitting claims for reimbursement by government payers for surgical services not in compliance with these rules and statutes, which are material, results in the submission of false claims in violation the False Claims Act.

30. Defendants submitted false claims to Medicare and other government-funded health insurance programs with full knowledge and awareness that such claims contained false statements, misrepresentations, misleading assertions, omissions, and "half-truths" that concealed material violations of Medicare statutory, regulatory and/or contractual requirements.

[15] See, 42 C.F.R. 415.172(b).

31. Had federal other government-funded health insurance programs known that Defendants' surgical procedures performed on Dr. Samadi's patients, as outlined above, were not eligible for reimbursement, they would not have reimbursed Defendants for such procedures. Operative regulations forbid such reimbursement, and the legislative history, past prosecutions, and guidance from CMS' Office of the Inspector General ("OIG") underscore the significance of these regulations and the importance of compliance. See *infra*, at ¶¶ 264-278.

32. In order to redress the foregoing violations on behalf of the United States of America, Relators bring this *qui tam* Amended Complaint against Defendants alleging federal false claims act violations arising from surgical services provided to Dr. Samadi's patients at Lenox Hill who are/were eligible to receive health care coverage provided by publicly funded insurance plans, including Medicare and TRICARE.

33. Prior to filing their initial Complaint, Relators provided information to the United States government in conformance with 31 U.S.C. §3730(b)(2).

II. PARTIES

34. Relator George Markelson (Relator Markelson) is the son of Stephen Markleson, deceased, and executor of his estate. Stephen Markelson was a patient of Defendant David B. Samadi, M.D.[16] George Markelson was present at Lenox Hill during his father's admission and has knowledge about the medical treatment, patient records, and billing related to his father's urologic care at Lenox Hill Hospital purportedly by Dr. Samadi. At all times relevant to this Amended Complaint, The Estate of Stephen Markelson, Deceased, resides and is domiciled at 70 Shore Road, Westhampton, New York 11977. Relator George Markelson, as Executor, resides and is domiciled at 76188 Overseas Highway, Islamorada, Florida 33036.

[16] *See,* discussion of decedent Stephen Markelson's surgery and treatment, *infra* at ¶¶ 157-183.

35. Relator Peter Nadler was a patient of Defendant David B. Samadi starting in the Spring of 2015. Mr. Nadler has first-hand knowledge of the care he received from Defendant Samadi, including, but not limited to, the events related to his outpatient treatment at Samadi's office, admission to Lenox Hill for surgery, the billing related to his treatment, subsequent urological treatment, and patient records pertaining to the care that he received at Lenox Hill.[17] At all times relevant to the Amended Complaint, Relator Nadler has resided and has been domiciled at 160 East 84th St., Apt. 6J, New York, New York 10028.

36. Relator Lorraine Waters is the wife of Relator Peter Nadler. She has knowledge about her husband's admission and treatment at Lenox Hill, including the TURP he received on June 22, 2015, the prior outpatient treatment by Dr. Samadi, the post-discharge treatment by Dr. Samadi, subsequent treatment by other physicians, and the billing related to this care. At all times relevant to the Amended Complaint, Relator Waters has resided and has been domiciled at 160 East 84th St., Apt. 6J, New York, New York 10028.

37. Defendant David B. Samadi, M.D. was and is a physician offering professional medical services and urology care and treatment to the public and patients in general, including Stephen Markelson, now deceased, and Peter Nadler in the State of New York. Dr. Samadi is licensed to practice medicine in the State of New York and board certified in the field of urology. During all times relevant to the Amended Complaint, Dr. Samadi is and was employed[18] by and affiliated with Defendants Lenox Hill Hospital and Northwell Health Inc. Dr. Samadi was the Chair of the Urology Department at Lenox Hill Hospital and the Director of the Urology Residency Program during the period July 1, 2013 – July 1, 2018.

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[17] *See,* discussion of Relator Nadler's surgery and treatment, *infra* at ¶¶ 126-156.

[18] Dr. Samadi has an employment contract with both Defendant Lenox Hill Hospital and Defendant Northwell Health, Inc.

38. Dr. Samadi is and was authorized to provide care and treatment to patients at Defendant Lenox Hill Hospital and at health care facilities owned, operated, managed and controlled by Defendants Lenox Hill Hospital and Northwell Health, Inc. Dr. Samadi's office is located at 485 Madison Avenue, 21st Floor, New York, NY 10022.

39. Defendant David B. Samadi, M.D., P.C., is a business that is owned, operated, controlled, managed and directed by Defendant David B. Samadi, M.D. Dr. Samadi is also employed by and the sole shareholder of the entity, which is a professional corporation with its principal place of business and principal executive offices located at 485 Madison Avenue, 21st Floor, New York, NY 10022.[19] At all times relevant to the Amended Complaint, David B. Samadi, M.D., P.C., was in operation.

40. Defendant Lenox Hill Hospital was and is a purported domestic "not-for-profit" corporation duly organized and existing pursuant to the laws of the State of New York. Defendant Lenox Hill Hospital's principal place of business and principal executive offices are located at 100 East 77th St. New York, NY 10075. Lenox Hill Hospital was and is a teaching hospital with ACGME certified and approved residency and fellowship training programs in various medical and surgical specialties, including a urology residency program.

41. Defendant Northwell Health, Inc. ("Northwell")[20] was and is a corporation with business operations in the State of New York consisting of a health care network that includes ownership, operation, control, management, direction and supervision of five teaching hospitals, ten community hospitals, three specialty care hospitals, the Hofstra Northwell School of Medicine, a medical research institute, outpatient health care facilities, rehabilitation facilities, skilled

[19] This party is also variously referred to as "David Samadi, P.C.," and "Samadi, P.C.," *infra.*
[20] This party is also variously referred to as "Northwell Health" or "Northwell" *infra.*

nursing facilities, a home care network, a hospice network and physician medical groups. Northwell owns, operates, controls, manages, directs and supervises all structural, financial and management decisions of defendant Lenox Hill Hospital and is the corporate alter ego of Defendant Lenox Hill Hospital. Northwell is a purported domestic "not-for-profit" corporation with its principal place of business and principal executive offices located at 145 Community Drive, Great Neck, NY 11021.

III. JURISDICTION AND VENUE

42. The Relators bring this action on behalf of themselves and the United States for violations of the False Claims Act, 31 U.S.C. §§ 3729-3733 and seek damages in connection with those violations.

43. This Court has federal subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732.

44. This Court has personal jurisdiction over Defendants, pursuant to 31 U.S.C. § 3732(a), because Defendants can be found in and transact business in this District. In addition, the acts prohibited by 31 U.S.C. § 3729 occurred in this District.

45. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendants transact business in this District and numerous acts proscribed by 31 U.S.C. § 3729 occurred in this District.

46. Relators' claims and this Amended Complaint are not based upon prior public disclosures of allegations or transactions in a federal criminal, civil, or administrative hearing in which the Government is already a party, or in a congressional, Government Accountability Office, or other federal report, hearing, audit, or investigation, or from the news media, as enumerated in 31 U.S.C. § 3730(e)(4)(A).

47. To the extent that there has been a public disclosure unknown to the Relators, each Relator is an "original source" under 31 U.S.C. § 3730(e)(4)(B). The Relators have independent material knowledge of the information on which the allegations are based and have voluntarily disclosed and given notice of the allegations in this action to the government, including a disclosure statement and all relevant evidentiary materials, prior to filing this *qui tam* action under seal based on that information. *Id.*

IV. STATUTORY AND REGULATORY PROVISIONS APPLICABLE TO DEFENDANTS' FALSE CLAIMS ACT VIOLATIONS

48. Defendant Lenox Hill Hospital is affiliated as a teaching hospital with the Hofstra Northwell School of Medicine and offers "residency and fellowship training programs in most of its clinical areas."

49. Defendants Lenox Hill Hospital and Northwell serve as the "institutional sponsor" for the urology residency program accredited by ACGME and provide salary and benefits to the urology residents.

50. The government spends significant dollars on GME programs, specifically $15 billion in FY 2015, because support of proper training is integral to maintaining a continued competent physician workforce to meet the nation's healthcare needs. According to a December 27, 2018 Congressional Research Service Report "access to healthcare is, in part, determined by the availability of physicians, a function of the physician supply."[21] That report noted that

> the federal government makes a significant investment in GME – according to the GAO [U.S. Government Accounting Office], GME programs account for nearly three-quarters of HHS's [U.S. Dept. of Health and Human Services] health workforce expenditures – and GME may be a strong policy lever to impact access because the number of medical school graduates who obtain and complete a

[21] "Federal Support for Graduate Medical Education: An Overview," p. 2, (found at https://fas.org/sgp/crs/misc/R44376.pdf)

> residency determines the size of the physician workforce, and the type of the residencies they complete determine its specialty composition.

Id. at p. 5.

51. The urology residents are physicians with M.D. degrees who come to Lenox Hill to train for two years in general surgery and four years in urology. Defendant Northwell's receipt of federal GME dollars is conditioned on accreditation by the ACGME. 42 C.F.R. 413.75(b) (defining "approved medical residency program").

52. One resident per year is chosen to train at Lenox Hill's urology residency program so that there are a total of four urology residents training at any one time in the program.

53. As providers of graduate medical education ("GME"), Defendants Lenox Hill and Northwell receive substantial payments from the United States government for resident physician training and salaries through direct and indirect graduate medical education payments under Medicare Part A.

54. This funding is provided in an annual grant by Medicare and amounts to approximately $250,000.00 per resident per year. The Medicare GME funding grant provided to Lenox Hill is based on the total number of residents at the institution. The grant is provided on the condition that Lenox Hill properly and adequately train and educate residents.

55. In addition, Defendants Lenox Hill and Northwell receive funding from other federal programs (collectively with payments under Medicare A "GME funds") to support their work in training residents.[22]

[22] Medicare Financing of Graduate Medical Education, Intractable Problems, Elusive Solutions, Rich, E.C., et al., J. Gen. Int. Med., 17: 283-292 (2002).

56. Defendants Lenox Hill and Northwell bill Medicare Part B for the services (such as surgeries) rendered by teaching physicians on its faculty incident to the instruction of residents provided that all Medicare regulations are followed.

57. Defendant Lenox Hill's urology residency program, including compliance with ACGME requirements, was the responsibility of Defendant Dr. Samadi who assumed the program directorship after he was hired by Northwell to be the urology department chairman in 2013.

58. ACGME provides accreditation of all residency and fellowship training programs at teaching hospitals in the United States; the ACGME periodically evaluates, assesses and inspects all such residency and fellowship programs.

A. GOVERNMENT HEALTH CARE PROGRAMS

59. The federal government, through Medicare and public employer health and welfare plans, are among the principal payers responsible for reimbursing Defendants for surgical services. Medicare is a federal government health program that primarily benefits the elderly and the disabled. It was created by Congress in 1965 when it adopted Title XVIII of the Social Security Act. Medicare is administered by CMS, which is an agency of the Department of Health and Human Services ("HHS").

60. Medicare Part A covers the cost of inpatient hospital services and post-hospital skilled nursing facility care. Medicare Part B covers the cost of the physician's services such as services to patients who are hospitalized, if the services are medically necessary and personally provided by the physician or, in the case of teaching hospitals, supervised by a physician where strict requirements are satisfied.

61. CMS establishes rules for the day-to-day administration of Medicare. CMS contracts with private companies to handle day-to-day administration of Medicare.

62. CMS, through contractors, maintains and distributes fee schedules for the payment of physician services. These schedules specify the amounts payable for defined types of medical services and procedures.

63. Hospitals generally are reimbursed under Medicare Part A on a reasonable cost basis for services provided to Medicare beneficiaries. Resident salaries are included among the costs for which hospitals are reimbursed under Part A; thus, services provided by residents typically cannot be billed under Medicare Part B.

64. As a teaching hospital, engaged in the training of medical students, residents and fellows ("trainees"), the hospital Defendants are eligible to be reimbursed for the teaching activities of clinical faculty physicians (also referred to herein as "teaching physicians"). Teaching hospitals may also properly bill under Medicare Part B for medical services of attending physicians in limited circumstances where the attending physician is directly involved in providing patient services.

65. The Federal Employees Health Benefits Program ("FEHBP") provides health insurance coverage for more than 8 million federal employees, retirees, and their dependents. FEHBP is a collection of individual health care plans, including Blue Cross and Blue Shield plans, Government Employees Hospital Association, and Rural Carrier Benefit Plan. FEHBP plans are managed by the U.S. Office of Personnel Management.

66. TRICARE is a federal program which provides civilian health benefits for military personnel, certain military retirees, and their families. TRICARE is administered by the Department of Defense and funded by the federal government.

67. At all relevant times to the Amended Complaint, applicable TRICARE regulations relating to coverage of claims by providers and physicians have been substantially similar in all material

respects to the applicable Medicare provisions described above. Medicare, FEHBP, TRICARE, and other similar federal and state medical insurance programs are referred to collectively herein as "government payers."

B. MEDICARE REIMBURSEMENT RULES

1. Medicare's Payment for Services of Attending Physician Services in a Teaching Setting

68. To participate in the Medicare Program, hospitals enter "provider agreements" with the HHS Secretary. *See* 42 U.S.C. § 1395cc. The Medicare Program pays the hospital directly for covered inpatient and outpatient services provided to Medicare beneficiaries except for any deductible or coinsurance, which is collected from the beneficiaries. *Id.*

69. When submitting claims for reimbursement on CMS Form 1500 to Medicare or TRICARE, the provider is required to certify, *inter alia*, that: 1) the information on this form is true, accurate and complete; 2) sufficient information is provided to allow the government to make an informed eligibility and payment decision; 3) the claim complies with all applicable Medicare laws, regulations, and program instructions for payment; and 4) the services on this form were medically necessary.[23] The form further requires the provider to certify that the services on the form were "personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare or TRICARE." *Id.*

70. In a teaching setting, in order to receive payment under Part B for services performed by a physician, the service must meet one of the following criteria: (a) the services are personally furnished by a physician who is not a resident; or (b) the services are furnished by a resident

[23] CMS Form 1500 (available at: https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf).

in the presence of a fully-licensed, teaching physician. 42 C.F.R. § 415.170(a)-(b). Section 415.170 is expressly designated a condition of payment. *See,* § 415.170 ("Conditions for payment on a fee schedule basis for physician services in a teaching setting.")

71. If a resident participates in a service furnished in a teaching setting, the service is eligible for a physician fee schedule payment "only if a teaching physician is present during the key portion of any service or procedure for which payment is sought." 42 C.F.R. § 415.172(a). This provision is a specific application of § 415.170. *See* 42 C.F.R. §§ 415.170(b) (services by a resident are not billable to Medicare Part B unless furnished in the presence of a teaching physician "except as provided in § 415.172)

72. In the case of surgical, high-risk, or other complex procedures – such as all the procedures at issue in this Amended Complaint – the teaching physician must be present during all critical portions of the procedure and immediately available to furnish services during the entire service or procedure. 42 C.F.R. § 415.172(a)(1).

73. If a teaching physician engages in two surgeries that overlap, the CMS Medicare Claims Processing Manual states, "[t]he critical or key portions *may not take place at the same time. When all of the key portions of the initial procedure have been* ***completed****, the teaching surgeon may begin to become involved in a second procedure.*" CMS 2018 Claims Manual at 100.1.2 (Surgical Procedures) A (Emphasis added).

74. While the key or critical parts of various surgical procedures may vary, CMS has specific guidance with regard to the endoscopic/laparoscopic surgeries at issue in this case (e.g., RALPs, TURPs, cystoscopy, ureteroscopies, etc.), which require the teaching physician to be

present for the "entire viewing" in the Operating Room: "the entire viewing starts at the time of insertion of the endoscope and ends at the time of removal of the endoscope."[24]

75. Moreover "[d]uring non-critical or non-key portions of the surgery, if the teaching surgeon is not physically present, he/she must be immediately available to return to the procedure, *i.e.*, *he/she cannot be performing another procedure.*" Medicare Claims Processing Manual, 100.1.2-A Surgical Procedures (Nov. 30, 2018)[25] (Emphasis added).

76. When a teaching physician is participating in a second surgical procedure and "not present during non-critical or non-key portions of the [prior] procedure … *he/she must arrange for another qualified surgeon*[26] *to immediately assist* the resident in the other case should the need arise." CMS 2011 Claims Manual at 100.1.2 (Surgical Procedures) A (Emphasis added). In short, the resident should not be conducting the surgery alone.

77. As summarized in the chart appended to the Senate Finance Committee Report, "Concurrent and Overlapping Surgeries: Additional Measures Warranted" (Dec. 6, 2016),[27] CMS defines concurrent surgeries as those where the critical or key parts of two surgeries are performed by the same teaching physician at the same time. The teaching physician is not allowed to bill for such surgeries. Overlapping surgeries are permitted as follows:

> [The] teaching physician must be present during the critical or key portions of both procedures. The teaching physician may become involved in a second procedure *when the key portions of the initial procedure have been completed.* If the teaching physician is not present during non-critical and non-key portions and is

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[24] *Id.* at 100.1.2.A.5. Endoscopy Procedures.
[25] Available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf (last viewed on February 25, 2019).
[26] CMS regulations require participating hospitals to "assure that personnel are licensed or met other applicable standards that are required by State or local laws." 42 C.F.R. §482.11(c) (Condition of participation; Compliance with Federal, State and local laws).
[27] See page 19 of the Appendix (hereafter "2016 Senate Finance Committee Report.") Available at www.finance.senate.gov/imo/media/doc/Concurrent%20Surgeries%20Report%20Final.pdf

> participating in another surgical procedure, she/he must arrange for another qualified surgeon to immediately assist in the other case should the need arise.

Id. at 19. Otherwise CMS will not pay.

78. The Senate Finance Committee Report notes that the American College of Surgeons (ACS) confirmed and clarified CMS's guidelines in its own clinical guidelines in April 2016. As the Report notes, the ACS guidelines expressly distinguish between overlapping and concurrent surgeries (p. 20, Appendix n.b):

> ACS defines concurrent surgeries as surgeries when the critical components of the operations for which the primary attending surgeon is responsible are occurring at the same time. ACS defines overlapping surgeries as surgeries when the critical components of the first operation have been completed and the primary attending surgeon performs critical portions of a second operation in another room. *While CMS's billing requirements generally do not refer to concurrent surgeries, those requirements make it clear that CMS will not pay physician fees for concurrent surgeries, as they are defined by ACS.*

Id. (Emphasis added).

79. CMS policy expressly limits payment to services for which there is documentation demonstrating the appropriate level of services required by the patient. *See* Medicare Carriers Manual, Part 3 CMS Pub. 14-3 (Rev. 1780); 42 C.F.R. § 415.172 *et seq.*; 60 Fed. Reg. 63124-01, 1995 WL 723389 (F.R.).

80. When a teaching physician seeks reimbursement for a service involving a resident in the care of his/her patients "it must be identified as such on the claim" and is not payable unless it complies with the Claims Processing Manual. CMS 2011 Claims Manual at 100.1.8 (Physician Billing in the Teaching Setting) at B.

81. Moreover, the "teaching surgeon must personally document in the medical record that he/she was physically present during the critical or key portion(s) of both procedures." 42 C.F.R. § 415.172; CMS 2011 Claims Manual at 100.1.2 (Surgical Procedures) A.2.

82. In sum, the teaching physician must appropriately document his/her involvement in the surgery when the resident performs elements of the surgery in the presence of, or jointly with, the teaching physician. The documentation must include sufficient information about the work performed during key portions of both procedures in the notes so that a "reviewer may clearly infer that the teaching physician was immediately available to return to either procedure in the event of complications." *Goldberg v. Rush Univ. Med. Ctr.*, 929 F. Supp. 2d 807, at 823 (N.D. Ill. 2013) (interpreting 2002 Medicare Claims Processing Manual).[28] Documentation is required when the surgery is concurrent with another surgery and appropriate supervision of the resident or fellow is lacking and, therefore, does not justify billing by or payment for the teaching physician. *Id.* Billing for a surgery that does not comply with the above Medicare rules is a false claim. *Id.*

83. Medicare providers are required to make restitution to the Medicare Programs when overpayments are identified unless the provider is without fault. See 42 U.S.C. § 1320a-7b(a)(3); see also 42 C.F.R. 405.350 *et seq.*; 42 C.F.R. § 489.20(b); OIG Compliance Guidance for Hospitals, 63 Fed. Reg. 8987, 8998 (Feb. 23, 1998).

2. ***Medicare Rules Pertaining to Reimbursement of Anesthesia***

84. Medicare reimburses anesthesia practitioners for the period of time during which they are "present with the patient." Medicare Claims Processing Manual at "50-Payment for Anesthesiology Services" (Rev. 4173, 11-30-18). Specifically, the billing period or "anesthesia time" begins "when the anesthesia practitioner begins to prepare the patient for anesthesia services in the operating room or an equivalent area and ends when the anesthesia practitioner

[28] 1996 Rules § 15016(C)(3)(a)(2) of the Medicare Claims Processing Manual (Transmittal 1780)(November 22, 2002). *See*, https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1780B3.pdf (last visited Feb 25, 2019).

is no longer furnishing anesthesia to the patient, that is, when the patient may be placed safely under postoperative care." *Id.*

85. Furthermore, anesthesia time is a "continuous" time block *and* the actual amount of time spent with the patient is "reported on the claim" for payment. *Id.* For computing payment, anesthesia time is divided into 15-minute increments and rounded up to one decimal place. *Id.*

86. Administering anesthesia to patients while they wait for extended periods for their surgeon to scrub in from another surgery – that is intentionally scheduled and conducted at the same time – is not reimbursable. This is because "no payment may be made [under the Medicare statute] for any expenses incurred for items or services which … are not *reasonable and necessary* for the diagnosis or treatment of illness or injury to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A) (Emphasis added).

87. It is not reasonable or necessary – and it is dangerous and risky – to place patients under general endotracheal anesthesia without medical justification.[29]

3. Medicare Reimbursement Rules Pertaining to Informed Consent

88. Ensuring that Medicare patients have given adequate informed consent prior to medical procedures is a condition of participation in the Medicare program. *See generally,* 42 C.F.R. § 482.13 (Condition of participation: Patient's rights). Obtaining proper informed consent is *also*

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[29] See, Comparison Between Spinal and General Anesthesia in Percutaneous Nephrolithotomy, Movasseghi, *et al.*, Anesth Pain Med., 2014, February; 4(1): e13871; Comparison of Postoperative Events between Spinal Anesthesia and General Anesthesia in Laparoscopic Cholecystectomy, Wang, *et al.*, BioMed Research International Volume 2016, 9 pages; Comparing Spinal and General Anesthesia in terms of Postoperative Pain in Patients undergoing Hysterectomy, Zorofchi *et al.,* Journal of Obstetrics, Gynecology and Cancer Research, 2018:3(2): 73-77; General Versus Spinal Anesthesia – Which is a Risk Factor for Octogenerian Hip Fracture Repair Patients?, Shih, *et al.*, Intl J Ger, March 2010, Vol 4, No 1; Comparison Between General Anesthesia and Spinal Anesthesia in Attenuation of Stress Response in Laparoscopic Cholecystectomy, Das, SJA, 2015, Apr – Jun 9:2, 184–188.

a condition of payment. Specifically, the CMS State Operations Manual states that "[h]ospitals are required to be in compliance with the federal requirements set for the Medicare Conditions of Participation (COP) *in order to receive Medicare/Medicaid payment.*" (Emphasis added) CMS – State Operations Manual – Regulations and Interpretive Guidelines for Hospitals (Rev. 151; 11-20-15).

89. Among other requirements, CMS COPs include numerous informed consent rules designed to protect Medicare and Medicaid patients. For example, patients must have involvement, *inter alia*, in their own plan of care and be offered the ability to refuse treatment. 42 C.F.R. § 482.13(b)(1) & (2). Medicare and Medicaid patients also have the "right to receive care in a safe setting." 42 C.F.R. § 482.13(c)(2). A "properly executed" informed consent form must be included in each patient's chart prior to surgery. 42 C.F.R. § 482.51(b)(2) (Condition of participation: Surgical services); *see also* 42 C.F.R. § 482.24(c)(2)(B)(v) (Condition of participation: Medical record services).

90. CMS's adoption of interpretive guidelines for informed consent highlights the importance of compliance and the centrality of appropriate informed consent to participation in the payment under Medicare. The "CMS Hospital Interpretive Guidelines for Informed Consent," extensively revised in 2007, state that a "well designed consent process" would, among other things, include:[30]

> A description of the proposed surgery, including the anesthesia to be used;
>
> The indications for the proposed surgery;

[30] April 13, 2007 CMS "Revisions to the Hospital Interpretive Guidelines for Informed Consent" at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter07-17.pdf (last visited February 26, 2019).

Material risks and benefits for the patient related to the surgery and anesthesia, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's clinical judgment. Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity;

Treatment alternatives, including the attendant material risks and benefits;

The probable consequences of declining recommended or alternative therapies;

Who will conduct the surgical intervention and administer the anesthesia;

Whether physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital's policies. Important surgical tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines.

For surgeries in which residents will perform important parts of the surgery, discussion is encouraged to include the following:

That it is anticipated that physicians who are in approved post graduate residency training programs will perform portions of the surgery, based on their availability and level of competence;

That it will be decided at the time of the surgery which residents will participate and their manner of participation, and that this will depend on the availability of residents with the necessary competence; the knowledge the operating practitioner/teaching surgeon has of the resident's skill set; and the patient's condition; and

Whether, based on the resident's level of competence, the operating practitioner/teaching surgeon will not be physically present in the same operating room for some or all of the surgical tasks performed by residents.

93. The 2016 Senate Finance Committee Report, at p. 10, pointed out that CMS's conditions of payment and corresponding interpretive guidelines:

> require hospitals to take certain steps to ensure that patients consent to planned surgeries. For example, this guidance states that a well-designed informed consent policy should include a discussion of a surgeon's possible absence during part of the patient's surgery, during which residents will perform surgical tasks, and that the informed consent policy should assure the patient's right to refuse treatment.

94. Obtaining a proper informed consent before surgery or an operative procedure is also a fundamental element of proper surgical practice; it is an essential component of "medically necessary" treatment. According to the American Medical Association (AMA):

> [a] surgeon who allows a substitute to operate on his or her patient without the patient's knowledge or consent is deceitful. The patient is entitled to choose his or her own doctor and should be permitted to acquiesce or refuse the substitution....
>
> Under the normal and customary arrangement with patients .... the operating surgeon is obligated to perform the operation but may be assisted by residents or other surgeons. With consent of the patient, it is not unethical for the operating surgeon to delegate the performance of certain aspects of the operation to the assistant provided this is done under the surgeon's participatory supervision, i.e., the surgeon must scrub. If a resident or other physician is to perform the operation under non-participatory supervision, it is necessary to make full disclosure of this fact to the patient, and this should be evidenced by an appropriate statement in the consent. Under these circumstances, it is the resident or other physicians who become the operating surgeon.[31]

95. Peer reviewed medical journal authorities have similarly stated:

> The substitution of an authorized surgeon by an unauthorized surgeon or the allowance of unauthorized surgical trainees to operate without adequate supervision constitutes 'ghost surgery'. These practices are legally and ethically iniquitous. Ghost surgery flies in the face of case law and violates an individual's right to control his or her own body and violates that person's right to information needed to make an informed decision. [32]

96. The Code of Ethics mandated by the American Urological Association pertaining to informed consents states, in pertinent part, as follows:

> I will consider *informed consent* integral to providing appropriate medical or surgical care. I recognize that my patient must be provided with *all of the information necessary to consent* and to make his own choice of treatment, regardless of my own advice or judgment. The information provided must include known risks and benefits, costs, reasonable expectations and possible complications, available alternative treatments and their cost, *as well as the identification of other medical personnel who will be participating directly in the*

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[31] See, AMA Council on Ethical and Judicial Affairs Opinion E-8.16, "Substitution of Surgeon Without Patient's Knowledge or Consent".

[32] See, Ghost Surgery: The Ethical and Legal Implications of Who Does the Operation, Kocher, MS, J Bone Joint Surg Am, 84: 148-150 (2002).

care delivery. Wherever feasible, I will respect my patient's rights and be limited by the scope of my patient's consent.[33]

4. ***Medicare Regulations Pertaining to Adequacy of Medical Records***

97. CMS regulations also address the issue of certain requirements that must be followed by health care providers with regard to certifying the accuracy of medical records (*e.g.*, operative reports, anesthesia records, operative case records, etc.) that serve as the basis of the claims for payment submitted to Medicare.

98. Medicare regulations require that medical records in surgical procedures, *e.g.*, operative reports, contain the name of the attending surgeon who actually performed the surgery or, alternatively, a statement that the attending surgeon was present for the "critical or key portions" of the surgery or present for the "entire viewing" portion of an endoscopic / laparoscopic surgery. *See* 42 C.F.R. § 415.172(b).

99. CMS policy expressly limits payment to services for which there is documentation demonstrating the appropriate level of services required by the patient. See Medicare Carriers Manual, Part 3 CMS Pub. 14-3 (Rev. 1780); 42 C.F.R. § 415.172 *et seq.*; 60 Fed. Reg. 63124-01, 1995 WL 723389 (F.R.).

5. ***The Government's Particular Interest: Graduate Medical Education***

100. The wrongdoing alleged in this complaint could not have occurred absent violations of the very ACGME rules required for accreditation of the Lenox Hill GME program; accreditation is necessary to secure federal funds. Hence the government has a material interest in the conduct alleged herein not just because it involved the submission of false claims for payment and approval but also because it compromised the government investment in medical

[33] See, https://www.auanet.org/myaua/aua-ethics/code-of-ethics (Emphasis added).

education. Moreover, Dr. Samadi's compensation for work that he did not perform – ensuring compliance with ACGME rules – constituted an additional kickback for the referral of services.

101. Medicare contributes the funds to pay the costs associated with approved GME programs. *See* 42 U.S.C. § 1395ww(h); 42 C.F.R. §§ 413.75, 413.76, 413.77, 412.105. Medicare pays for both direct ("DME") and indirect ("IME") costs of GME programs.

102. Payments for DME, among other things, help cover the costs incurred by hospitals for medical residents and teaching faculty, including salaries, fringe benefits, and allocations of overhead. Calculation of Medicare's share of the DME amount is obtained by multiplying the number of Full-Time Resident Equivalents by the authorized per-resident amount and then multiplying that result by the hospital's Medicare patient load. *See* 42 C.F.R. §§ 413.76, 413.77. These Medicare amounts are calculated and paid based on information included in the hospital's cost report.

103. Payments for IME are intended to cover the additional incremental costs associated with the more intensive care, aggressive treatment and increased availability of state of the art testing technologies found in teaching hospitals and related to the training of residents.

104. Calculation of Medicare's share of the IME amount is based on information included in the hospital's cost report and utilizes a complex formula established by regulation. *See* 42 C.F.R. § 412.105.

105. The hospital cost reports are submitted on a CMS-approved form that contains both an advisory and a certification of truth and accuracy. The advisory states:

> MISREPRESENTATION OR FALSIFICATION OF ANY INFORMATION CONTAINED IN THIS COST REPORT MAY BE PUNISHABLE BY CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, AND/OR IMPRISONMENT UNDER FEDERAL LAW. FURTHERMORE, IF SERVICES IDENTIFIED IN THIS REPORT WERE PROVIDED OR PROCURED THROUGH THE PAYMENT DIRECTLY OR INDIRECTLY OF A KICKBACK

OR WERE OTHERWISE ILLEGAL, CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINES AND/OR IMPRISONMENT MAY RESULT.

106. The certification, which appears immediately below the advisory, states:

> I hereby certify that I have read the above statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by (the hospital) for (the relevant cost reporting period) and to the best of my knowledge and belief, it is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services and that the services identified in this cost report were provided in compliance with such laws and regulations.

107. Hospitals must have approved graduate medical education programs to qualify for DME and IME payments under the Medicare GME funding programs. In the field of urology, an "approved" program is a residency program approved by the ACGME. *See* 42 C.F.R. §§ 413.75(b), 415.152. The ACGME is authorized by regulation to approve hospitals that sponsor residency programs that demonstrate compliance with the standards and requirements for that program. "Approval" is the recognition accorded residency programs that are determined to be in substantial compliance with such standards and requirements. Approval is based on an overall evaluation of the program and periodic review by the ACGME.

108. The urology residency program standards and requirements for approval are published in the ACGME Program Requirements for Graduate Medical Education in Urology. The standards and requirements include proper and adequate supervision, training and education in "ACGME Competencies," and "Patient Care and Procedural Skills" that encompass "all medical, diagnostic and surgical procedures" considered essential for practice in the field of urology. The training and education must include "core techniques," one required "core technique" is "minimally-invasive intra-abdominal and pelvic surgical techniques including,

laparoscopy and robotics." Moreover, the "supervision and accountability" of urology residents must conform to standards that include the requirement that "residents and faculty members must inform each patient of their respective roles in that patient's care when providing direct patient care."[34]

109. In pertinent part, the ACGME Program Requirements for Graduate Medical Education in Urology, include the following standards and requirements:

> IV.A.5. ACGME Competencies
>
> The program must integrate the following ACGME competencies into the curriculum:
>
> IV.A.5.a) Patient Care and Procedural Skills
>
> .....
>
> IV.A.5.a).(2) Residents must be able to competently perform all medical, diagnostic and surgical procedures considered essential for the area of practice.
>
> Residents:
>
> .....
>
> IV.A.5.a).(2).(e) must develop competence in the following core techniques:
>
> IV.A.5.a).(2).(e).(i) endo-urology; (Outcome)
>
> IV.A.5.a).(2).(e).(ii) major open flank and pelvic surgery; (Outcome)
>
> IV.A.5.a).(2).(e).(iii) microsurgery; (Outcome)
>
> IV.A.5.a).(2).(e).(iv) minimally-invasive intra-abdominal and pelvic surgical techniques including, laparoscopy and robotics; (Outcome)
>
> IV.A.5.a).(2).(e).(v) perineal and genital surgery; and, (Outcome)

[34] See, ACGME Program Requirements for Graduate Medical Education in Urology, IV.A.5., IV.A.5.a), IV.A.5.a).(2), IV.A.5.a).(2).(e), IV.A.5.a).(2).(e).(iv), pages 14-15 (available at https://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/480_urology_2017-07-01.pdf)(Emphasis added).

IV.A.5.a).(2).(e).(vi) urologic imaging including fluoroscopy, interventional radiology, and ultrasound..

VI.A.2. Supervision and Accountability

.....

VI.A.2.a).(1).(b) Residents and faculty members must inform each patient of their respective roles in that patient's care when providing direct patient care. (Core)

See, ACGME Program Requirements for Graduate Medical Education in Urology, pages 14-15. (Emphasis added).

C. THE STARK LAW AND ANTI-KICKBACK STATUTE

110. The Stark law, 42 U.S.C. § 1395nn *et. seq.*, seeks to prohibit physicians from referring Medicare patients (and other patients enrolled in government-funded health insurance programs) for designated health services ("DHS") to any entity with which they have a financial relationship, including a compensation arrangement, and to prohibit that entity from submitting claims that result from such referrals. DHS includes inpatient and outpatient hospital services. *Id.* § 1395nn(h)(6)(K).

111. The Stark law provides that no payment shall be made for DHS provided in violation of the statute. 42 U.S.C. § 1395nn(g)(1). Any person who collects funds billed in violation of the statute may be liable for civil money penalties and "shall refund on a timely basis . . . any amounts" collected in violation of the statute. *See id.* §§ 1395nn(g)(2)-(3); 42 C.F.R. § 411.353(d) ("An entity that collects payment for a [DHS] that was performed pursuant to a prohibited referral must refund all collected amounts on a timely basis."). The regulations implementing the Stark Statute define a "timely basis" as "the 60-day period from the time the prohibited amounts are collected by the individual or the entity." 42 C.F.R. § 1003.101.

112. "The Stark Law is intended to prevent physicians' financial interests from affecting whether they refer patients for outpatient procedures and where the patient is referred." *Council*

for Urological Interests v. Burwell, 790 F.3d 212, 225 (D.C. Cir. 2015) (citing 144 Cong. Rec. E4-03 (daily ed. Jan. 27, 1998) (statement of Rep. Stark) (noting that the Stark Law was "designed to reduce or eliminate the incentives for doctors to over-refer patients to services in which the doctor has a financial relationship")).

113. If violated, the Stark Law imposes strict liability; proof of specific intent is not required.[35]

114. There are exceptions to the Stark Law, none of which apply in the instant case.

115. The Anti-Kickback Statute,42 U.S.C. § 1320a-7b(b), prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by government payers, including Medicare.

116. "Renumeration" is broadly defined to include anything of value (including any kickback, bribe, or rebate) paid directly or indirectly, overtly or covertly, in return for purchasing, ordering or recommending the purchase of any item that is reimbursable." 42 C.F.R.§ 1001.952(f).

117. The Balanced Budget Act of 1997 amended the Medicare Anti-Kickback Statute to include administrative civil penalties of up to $50,000 for each act violating the Anti-Kickback Statute, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of that

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[35] *See, e.g.*, Center for Medicare and Medicaid Services, Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 72 Fed. Reg. 51,011 (CMS Sept. 5, 2007) (explaining that, unlike the FCA and the Anti-Kickback law, both of which include an intent element, the Stark law "is a strict liability statute"); Health Care Financing Administration, Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 66 Fed. Reg. 855, 859 (HCFA Jan. 4, 2001) ("Significantly, no wrongful intent or culpable conduct is required [for a Stark law violation to occur]."); *United States ex rel. Villafane v. Solinger*, 543 F. Supp. 2d 678, 685 (W.D. Ky. 2008) (same, quoting regulations); *see also Solinger*, 543 F. Supp. 2d at 687 (concluding that the "[HCFA and CMS] regulations are reasonable and permissible constructions of the Stark law, deserving of deference by this Court") (quoting *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984)).

amount was offered, paid, or received for a lawful purpose. *See* 42 U.S.C. § 1320a-7a(a)(10).

118. The purpose of the Anti-Kickback Statute is to ensure proper medical treatment and referrals, and to limit unnecessary treatment, services, or goods that are based not on the needs of the patient but on improper incentives given to others, thereby limiting the patient's right to choose proper medical care and services.

119. The Anti-Kickback Statute contains statutory exceptions and certain regulatory "safe harbors" that exclude certain types of conduct from the reach of the statute. *See, e.g.*, 42 U.S.C. § 1320a-7b(b)(3). However, none of the statutory exceptions or regulatory safe harbors protect the Defendants' conduct in this case.

120. In 2003, the HHS OIG issued its "Compliance Program Guidance for Pharmaceutical Manufacturers" (the "2003 Guidance"), which explained that "practices that may be common or longstanding in other businesses are not necessarily acceptable or lawful when soliciting federal health care program business," and that such practices would be illegal if "any *one* purpose of the remuneration [is] to induce or reward the referral or recommendation of business payable in whole or in part by a federal health care program. Importantly, a lawful purpose will not legitimize a payment that also has an unlawful purpose." *Id.* at 13, 14 (emphasis in original). While the Guidance is specifically directed at Pharmaceutical Manufacturers, the "one purpose test" has been applied by Courts in other contexts. The 2003 Guidance identified several questions that should be asked to determine if a practice violates the Anti-Kickback Statute, including:

- Does the arrangement or practice have a potential to interfere with, or skew, clinical decision-making?
- Does the arrangement or practice have a potential to increase costs to the federal health care programs, beneficiaries, or enrollees?

- Does the arrangement or practice have a potential to increase the risk of overutilization or inappropriate utilization?
- Does the arrangement or practice raise patient safety or quality of care concerns?

Id. at 1.

121. As set forth in this Amended Complaint, the answer to each of these questions with respect to Defendants' conduct is "Yes."

122. In 2010, the Patient Protection and Affordable Care Act ("PPACA"), Public Law No. 111-148, Sec. 6402(g), amended the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), to specifically allow violations of its "anti-kickback" provisions to be enforced under the False Claims Act, discussed next. The PPACA also amended the statute's "intent requirement" to make clear that violations of the anti-kickback provisions, like violations of the False Claims Act, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." *Id.* at Sec. 6402(h).

D. THE FALSE CLAIMS ACT

123. The Federal False Claims Act provides that any person who (1) knowingly presents or causes another to present a false or fraudulent claim for payment or approval, or (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim is liable for a civil penalty of between $5,500 and $11,000[36] for each such claim, plus three times the amount of the damages sustained by the government. 31 U.S.C. § 3729(a)(1)(A) & (a)(1)(B).

[36]As adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461; *see also* 84 F.R. 66, at 13520 (DOJ Apr. 5, 2019) (explaining 2019 amounts are unchanged from 2016 amounts); 81 F.R. 126, at 42491 (DOJ June 30, 2016) (setting forth 2016 increases).

124. The FCA also contains a "reverse-false-claims" provision, which hold liable persons or corporations who knowingly retain overpayments from the government. 31 U.S.C. § 3729 (a)(1)(G).

V. STATEMENT OF FACTS

A. Relator Nadler's Surgery – False Claims For Services That Did not Comply With Medicare Rules

125. Relator Nadler was Dr. Samadi's patient starting in Spring 2015. At the time, Mr. Nadler, was a 66-year-old patient covered by Medicare and United Healthcare, his wife's private commercial health insurance policy provided by her employer. Mr. Nadler was responsible for corresponding co-payments.

126. Relator Nadler saw Dr. Samadi's advertisements in the mass media and on the internet describing in extravagant terms that he was "the best in the world" among urologists and "NY's best prostate surgeon."

127. Indeed, Defendants Lenox Hill and Northwell heavily advertised Defendant Dr. Samadi's urology services; purportedly spending approximately $70,000.00 a month primarily for internet advertising related to Dr. Samadi's services.

128. For example, the "department of urology" on Lenox Hill's website directs to a page that touts only Dr. Samadi's services, the contact information for Dr. Samadi's private urology practice (*i.e.*, David B. Samadi, M.D., P.C.), and provides various resource links directed to "Lenox Hill Prostate Cancer Center" and "Robotic Oncology.com." "Lenox Hill Prostate Cancer Center" and "Robotic Oncology.com" also exclusively advertise Dr. Samadi's services and similarly provide the contact information for Dr. Samadi's private urology practice.

"Lenox Hill Prostate Cancer Center" and "Robotic Oncology.com" are merely "trade names" and "d/b/a's" for David B. Samadi, M.D., P.C.[37]

129. After viewing Dr. Samadi's advertisements, Relator Nadler saw Dr. Samadi for lower urinary tract symptoms ("LUTS") including difficulties in voiding his bladder, weak urinary stream, incomplete bladder emptying, marked hesitancy, interruptions in urinary flow, low urinary outflow rate and volume, extreme nocturia (4-5 times per night), pain, and discomfort.

130. Dr. Samadi diagnosed Relator Nadler with BPH[38] and recommended that he undergo a TURP, which was scheduled at Lenox Hill on June 22, 2015.

131. Dr. Samadi led Relator Nadler to believe that he would personally perform the TURP; he deceptively misrepresented to Nadler that he would "personally" operate on him and resolve Relator Nadler's troublesome complaints.

132. Dr. Samadi never informed and advised Relator Nadler that a urology resident was going to perform the TURP unsupervised while Dr. Samadi performed a RALP on a different patient in another O.R.

133. Relator Nadler would never have consented to the TURP had Dr. Samadi informed or advised him of the truthful, honest and accurate circumstances of performing the TURP. The TURP was performed by an unsupervised second-year resident, Johnson Tsui, M.D., in O.R. 21 while Dr. Samadi was performing a RALP on another patient in O.R. 25.

134. The consent form for Relator Nadler's TURP states that he consents to Dr. Samadi performing the surgery; neither Dr. Tsui nor any other "assistant" or "resident" is specifically

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[37] The only other attending urologists identifiable and advertised on Defendant Lenox Hill Hospital's website are Boback M. Berookhim, M.D., and Michael Feuerstein, M.D. They are Defendant Dr. Samadi's business associates and employees of Defendant David B. Samadi, M.D., P.C.

[38] BPH is Benign Prostatic Hyperplasia, an enlargement of the prostate gland.

named or identified as the surgeon performing the surgery or even participating in it. On June 22, 2015, Dr. Samadi had "double-booked" (concurrent) urologic surgeries on Relator Nadler and another patient in O.R. 21 and O.R. 25. The surgery in O.R. 25 was a RALP. The surgery in O.R. 21 on Relator Nadler was a cystoscopy / TURP. Both of these surgeries are considered to be endoscopic / laparoscopic surgeries.

135. Dr. Tsui performed the TURP on Relator Nadler in O.R. 21 on June 22, 2015, without supervision since an attending urologist was not present as required for the "entire viewing" during this endoscopic surgery and Dr. Samadi was in O.R. 25 performing the RALP. Moreover, Dr. Samadi failed to arrange for a qualified attending physician to be immediately available to take over the surgery, in case the resident needed assistance.

136. Dr. Tsui performed the TURP on Relator Nadler in O.R. 21 while he was under general anesthesia, which is not indicated or medically necessary for this type of surgery. Moreover, the duration of the TURP on Relator Nadler was excessive: two (2) hours; TURPs should normally be conducted within one hour.

137. Dr. Samadi did not supervise Tsui during the TURP on Relator Nadler since he was not present in O.R. 21 for the "entire viewing" and was not present for the "critical and key portions" of this endoscopic surgery.

138. On June 22, 2015, the TURP performed on Relator Nadler in O.R. 21 was concurrent with two other surgeries – RALPs – performed on two other patients of Dr. Samadi in O.R. 25.

139. A patient of Dr. Samadi's underwent a RALP in O.R. 25 that started at 6:50 a.m. and ended at 9:29 a.m.

140. Relator Nadler's TURP was performed in O.R. 21; his surgery started at 8:50 a.m. and ended at 10:53 a.m. Another patient of Dr. Samadi's underwent a RALP in O.R. 25 that started

at 9:50 a.m. and ended at 12:45 p.m. The TURP performed on Relator Nadler in O.R. 21 – two hours in duration – was concurrent for all but 21 minutes of the two RALPs performed on Dr. Samadi's patients in O.R. 25; therefore, 101 out of a total of 123 minutes of operative time on Relator Nadler in O.R. 21 occurred at the same time as the two surgeries in O.R. 25 (*i.e.*, 82%).

141. These three surgeries were essentially concurrent surgeries because Dr. Samadi could not have been present for the entire viewing during Relator Nadler's TURP. Indeed, the operative report on Relator Nadler's TURP on June 22, 2015, was dictated by Dr. Tsui but edited and electronically signed by Dr. Samadi on June 29, 2015 (*i.e.*, one week later). The Nadler operative report falsely states that Dr. Samadi was the "surgeon" and Dr. Tsui was the "assistant surgeon," when, in fact, Dr. Tsui was a resident at the time and Dr. Samadi did not meet the supervision requirements under the Medicare rules. The operative report for Relator Nadler's TURP on June 22, 2015, does not state that Dr. Samadi was present for the "critical or key portions" or the "entire viewing" portion of the procedure.

142. Dr. Tsui also prepared an operative summary progress note for Relator Nadler's TURP on June 22, 2015.

143. According to the operative report and operative summary, there was no indication that Tsui observed any obstruction within Relator Nadler's prostatic urethra during the cystoscopic portion of the TURP.

144. Dr. Tsui removed only 5 grams of prostatic tissue during the TURP performed on Relator Nadler according to the surgical pathology report. Dr. Tsui improperly performed the TURP because the 5 grams of tissue removed from Relator Nadler's prostate was and is inadequate for patients with obstructive BPH; therefore, the surgical procedure performed by the unsupervised resident was non-therapeutic and without any medical benefit to the patient.

145. In summary, Dr. Tsui deviated from proper urology practice by failing to remove a therapeutic amount of prostatic tissue from Relator Nadler that did not alleviate the urinary tract obstruction, but rather ultimately worsened it by causing scarring and overgrowth of BPH into the urethra. Relator Nadler did not obtain relief of his LUTS as a result of the faulty TURP by Dr. Tsui and, instead, suffered more severe complaints and worsened urinary tract function postoperatively than that which initially brought him to seek treatment from Dr. Samadi. There also was no medical justification for using general anesthesia on Relator Nadler for the TURP.

146. Relator Nadler was not only unnecessarily subjected to general anesthesia and excessive anesthesia time; but the Defendants billed Medicare for this unnecessary anesthesia service.

147. Notwithstanding Dr. Samadi's failure to follow Medicare's supervision, informed consent, and medically necessary treatment requirements, Defendants Dr. Samadi, Lenox Hill and Northwell unlawfully billed Medicare[39] for the TURP, hospitalization, anesthesia services and other related medical treatment.

148. The course of Mr. Nadler's treatment with Dr. Samadi also raises "double-dipping" issues, *i.e.*, performing certain operative procedures in a manner to ensure the necessity of a subsequent surgery and inpatient hospital admission as a means to increase surgical volume, billing revenue, and profits.

149. "Double-dipping" practices are designed to ensure continued "churning" of billing revenue from patients with private health insurance or Medicare coverage.

150. Prior to Mr. Nadler's TURP on June 22, 2015, Dr. Samadi had the patient undergo a prostate biopsy on May 15, 2015.

[39] United Health Care and Relator Nadler also paid for some of the treatment he received.

151. The prostate biopsy specimens were sent by Dr. Samadi to Bostwick Laboratories for pathology examination and diagnosis rather than Lenox Hill's own pathology department. Bostwick Laboratories has a questionable history: On January 8, 2016, the owner of Bostwick Laboratories agreed with the U.S. Department of Justice to pay a $3.75 million settlement related to claims of Medicare and Medicaid fraud.

152. The Bostwick Laboratories' pathology report on Mr. Nadler's specimens that was sent to Dr. Samadi not only indicated BPH (an indication for a TURP with severe obstructive lower urinary tract symptoms due to a prostatic urethral obstruction) but also "atypical small acinar proliferation" – a cellular marker potentially indicative of early prostate cancer. During postoperative visits, Dr. Samadi advised Mr. Nadler that he would need to undergo repeat prostate biopsies every six (6) months to check for prostate cancer due to the "atypical small acinar proliferation."

153. Mr. Nadler eventually left Dr. Samadi's care in 2016 after his complaints to Samadi about more severe postoperative LUTS symptoms went unaddressed and untreated. Mr. Nadler came under the care of another Lenox Hill attending urologist, Noel A. Armenakas, M.D., who ordered a repeat prostate biopsy after reading Dr. Samadi's medical records and noting the Bostwick Laboratories' pathology report finding of "atypical small acinar proliferation."

154. Dr. Armenakas performed Mr. Nadler's repeat biopsy on March 30, 2016, and sent the biopsy specimens to a different pathology laboratory, CBLPath, for analysis and diagnosis. The CBLPath pathology report on Mr. Nadler's biopsy specimens that was sent to Dr. Armenakas indicated that all cores showed "benign prostate tissue" and were negative for "atypical small acinar proliferation."

155. Dr. Armenakas advised Mr. Nadler that periodic repeat prostate biopsies were not necessary since the pathology report showed that he did not have "atypical small acinar proliferation." If Relator Nadler had remained Dr. Samadi's patient, Dr. Samadi and Bostwick Laboratories would have received substantial billing revenue related to his repeat prostate biopsies; however, the fortuitous circumstances of his terminating the doctor-patient relationship with Dr. Samadi and coming under the care of Dr. Armenakas led to the discovery that he did not have "atypical small acinar proliferation" and would not need to undergo repeat prostate biopsies every 6 months.

B. Stephen Markelson's Surgery - False Claims For Services That Did Not Comply With Medicare Rules

156. Plaintiff-Relator's decedent, Stephen Markelson, was Dr. Samadi's patient in October 2013. At the time, Mr. Markelson was a 79-year-old patient covered by Medicare and Blue Cross, his private commercial health insurance. Mr. Markelson was responsible for corresponding co-payments incurred by medical expenses.

157. Mr. Markelson was an inpatient at Lenox Hill Hospital admitted for cardiovascular problems when he developed intermittent hematuria, *i.e.*, blood in his urine, and a retained blood clot in the bladder.

158. Mr. Markelson's attending cardiologist requested a urology consultation from Dr. John Fracchia, an experienced attending urologist who had been LHH chairman of urology for 25 years. After the attending cardiologist requested Dr. Fracchia to perform this consultation, hospital personnel approached the elderly Markelson and his wife, Ann, and redirected the consultation to Dr. Samadi.

159. Dr. Samadi came to see Mr. Markelson in his hospital room; Samadi recommended a TURP and scheduled Markelson for surgery at Lenox Hill Hospital on October 30, 2013. Dr.

Samadi fraudulently led Markelson, his wife, and his son (Relator George Markelson) to believe that he would personally perform the TURP.

160. Dr. Samadi never informed and advised Mr. Markelson and his family that a urology resident was going to perform the TURP unsupervised while Dr. Samadi performed RALPs on other patients in O.R. 25.

161. Mr. Markelson would never have consented to the TURP had Dr. Samadi informed or advised him of the truthful, honest and accurate circumstances of a resident performing the TURP without appropriate supervision by Dr. Samadi. On October 30, 2013, Mr. Markelson underwent a cystoscopy / TURP at Lenox Hill Hospital in O.R. 21.

162. The cystoscopy / TURP was performed by an unsupervised second-year resident, Dr. Billy Cordon, in O.R. 21 while Dr. Samadi was performing a RALP on another patient in O.R. 25.

163. The cystoscopy / TURP performed on Mr. Markelson by Cordon in O.R. 21 was entirely or completely "simultaneous" or "concurrent" with a RALP performed by Dr. Samadi in O.R. 25 (*i.e.*, the TURP by Cordon was encompassed by the RALP) since Mr. Markelson's TURP in O.R. 21 started at 13:40 and ended at 15:50 while the other patient's RALP in O.R. 25 started at 13:40 and ended at 17:04.

164. The consent form for Mr. Markelson's TURP states that he consents to Dr. Samadi performing the surgery; neither Dr. Cordon nor any other "assistant" or "resident" is specifically named or identified as the surgeon performing the surgery or even participating in the surgery.

165. On October 30, 2013, Dr. Samadi had "double-booked" seven (7) urologic surgeries on his patients in both O.R. 25 and O.R. 21. The surgeries in O.R. 25 were all RALPs. The surgeries in O.R. 21 were TURPs, cystoscopies and ureteroscopies.

166. The multiple "double-booked" urologic surgeries performed on Dr. Samadi's patients in O.R. 25 and O.R. 21 on October 30, 2013, were all "concurrent" or "simultaneous" surgeries except for one RALP.

167. The multiple "double-booked" urologic surgeries performed on Dr. Samadi's patients in O.R. 25 and O.R. 21 on October 30, 2013, were all considered endoscopic / laparoscopic urologic surgeries.

168. Two (2) of the multiple "double-booked" urologic surgeries and operative procedures performed on Dr. Samadi's patients in O.R. 25 and O.R. 21 on October 30, 2013, involved Medicare patients. The remainder of the surgical procedures performed on Dr. Samadi's were performed on patients whose treatment was covered by private commercial health insurance plans.

169. Dr. Cordon performed the cystoscopy / TURP on Mr. Markelson in O.R. 21 without appropriate supervision since an attending urologist was not present as required for the "entire viewing" during this endoscopic surgery.

170. Mr. Markelson's surgery was conducted while he was under general anesthesia, even though this type of anesthesia is and was not medically necessary for a TURP.

171. Moreover, the duration of the TURP on Mr. Markelson lasted more than two (2) hours, which is about an hour longer than most TURP's require.

172. Dr. Samadi did not supervise Dr. Cordon during the TURP on Mr. Markelson as he could not possibly have been present in O.R. 21 for the "entire viewing" and was not present for the "critical and key portions" of this endoscopic surgery.

173. The operative report on Markelson's TURP falsely states that Dr. Samadi was the "surgeon" and Dr. Cordon was the "assistant surgeon;" Dr. Samadi signed the operative report.

Dr. Samadi's signing of the operative report purports to certify that he performed the surgery on Mr. Markelson; however, Dr. Samadi was elsewhere in O.R. 25 performing a RALP on another patient at the same exact time.

174. The operative report does not state that Dr. Samadi was present for the "critical or key portions" of the procedure or the "entire viewing" portion of the procedure. The operative report indicates that Mr. Markelson's prostate was markedly enlarged at 150g – 200g and that he was suffering from intermittent hematuria and a retained blood clot. It also indicates difficulty in controlling bleeding during the procedure. Several days after Mr. Markelson's TURP on October 30, 2013, he returned to Lenox Hill Hospital's E.R. with severe hematuria that would not stop.

175. Subsequently, Mr. Markelson was brought to the operating room for an open radical prostatectomy by Jay Motola, M.D., to remove the entire prostate to stop the bleeding; Dr. Motola performed this surgery because Dr. Samadi was on a trip outside of New York and no other attending urologist was available to step in to operate.

176. Dr. Samadi's decision to have Mr. Markelson undergo a TURP by a resident, Dr. Cordon, was erroneous, negligent and contraindicated because the TURP was guaranteed to result in a recurrence of bleeding in this elderly patient. A TURP on a patient like Mr. Markelson with a prostate as large as 150g – 200g with chronic intermittent hematuria is contraindicated due to the high risk of postoperative hemorrhage. Moreover, Mr. Markelson had a mechanical aortic valve that required daily anticoagulation medication.

177. Severe hematuria (*i.e.*, postoperative hemorrhage) that was potentially life threatening occurred after Mr. Markelson's TURP because the surgery had been performed despite

contraindications. Under the circumstances, an open radical prostatectomy was indicated for Mr. Markelson on October 30, 2013, rather than the TURP.

178. Mr. Markelson was also improperly subjected to general anesthesia and excessive anesthesia time on October 30, 2013; the Defendants billed Medicare and private insurance for this unnecessary anesthesia service.

179. Notwithstanding Dr. Samadi's failure to follow Medicare rules pertaining to supervision of residents, informed consent, and medical necessity, Defendants Dr. Samadi, Lenox Hill and Northwell unlawfully billed Medicare for the TURP, hospitalization, anesthesia services and other related medical treatment.

180. Dr. Samadi's actions with regard to the courses of treatment for Mr. Markelson is also indicative of "double-dipping" medical practices.

181. Dr. Samadi's recommendation of a TURP for an elderly patient like Mr. Markelson with chronic intermittent hematuria, a grossly enlarged prostate (200g) and daily anticoagulation for a mechanical aortic valve was contraindicated since it would necessarily raise a very high risk for recurrent postoperative bleeding requiring treatment by an open radical prostatectomy and inpatient hospital admission.

182. Mr. Markelson did, in fact, sustain a postoperative hemorrhage, required an open radical prostatectomy, and needed to be admitted to Lenox Hill. The fortuitous circumstances of Dr. Samadi being away from New York on a trip at the time Mr. Markelson returned to Lenox Hill with a hemorrhage and was readmitted to the hospital resulted in the billing revenue for the attending surgeon's services to go to Dr. Motola; however, the billing revenue for the inpatient hospital admission went to Lenox Hill and Northwell.

C. THE NORTHWELL / LHH UROLOGIC SURGERY DATABASES AND O.R. SCHEDULES

183. The Lenox Hill / Northwell urologic surgery databases and other operating room records demonstrate and corroborate the existence of the concurrent surgery scheme perpetrated by the Defendants, at least from July 2013 - 2016. Prior to that time, between 2004 and June 2013 (*i.e.*, pre-dating Dr. Samadi's tenure at Lenox Hill), there were no concurrently scheduled surgeries.

184. For example, from July 1, 2013 – August 31, 2016, there were 2,182 patients scheduled for urologic surgeries by Dr. Samadi. Of those surgeries, 1,207 (*i.e.*, approximately 55% of the total surgeries) violated the Medicare rules pertaining to supervision of residents because the duration of the operative procedure in O.R. 21 was entirely concurrent[40] with the operative procedure in O.R. 25 or the majority of the operative procedure[41] was concurrent with the O.R. 25 procedure.

185. During the same period, 424 urologic surgeries (*i.e.*, approx. 20% of the total surgeries) on Dr. Samadi's patients at LHH that constituted "simultaneous" or "concurrent" surgeries in which the time of the operative procedure in O.R. 21 was entirely or totally encompassed by the operative procedure in O.R. 25; *i.e.*, the surgery in O.R. 25 started before the start of the surgery in O.R. 21 and the surgery in O.R. 25 ended after the end of the surgery in O.R. 21.

186. During the same period, 783 urologic surgeries (*i.e.*, approximately 36% of the total surgeries) constituted "simultaneous" or "concurrent" surgeries because the time of the

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[40] The terms "entirely concurrent" or "totally concurrent" are defined as surgeries in O.R. 21 and O.R. 25 that are 100% concurrent.

[41] The term "majority of the operative procedure" is defined as surgeries in O.R. 21 and O.R. 25 that are 65% concurrent or greater since this degree of concurrence would necessarily preclude Dr. Samadi's presence for the "entire viewing" in a TURP or other endoscopic operation in O.R. 21; this term is with "mostly" or "significantly" concurrent and has the same definition.

operative procedure in O.R. 21 was mostly or significantly encompassed by the operative procedure in O.R. 25; *i.e.*, the start and end times of the surgeries in O.R. 25 and O.R. 21 were contemporaneous or synchronous for all but a short duration of time.

187. Moreover, during the same period, 1,530 urologic surgeries (*i.e.*, approximately 70% of the total surgeries) constituted "overlapping" surgeries, *i.e.*, the time of the operative procedure in O.R. 21 was encompassed to a degree of 65% concurrent or greater by the operative procedure in O.R. 25.

188. An example illustrating the Defendants' "concurrent" surgery scheme is the date of March 5, 2014, when surgeries were performed on eleven (11) of Dr. Samadi's patients at Lenox Hill; 10 out of the 11 surgeries were concurrent.

189. Specifically, Dr. Samadi performed five (5) RALPs in O.R. 25 and the residents performed six (6) non-RALP urologic surgeries in O.R. 21, as the chart below shows:

Anesthesia Start Time	**Anesthesia End Time**	**Dur-ation**	**OR**	**Patient Financial Class (Payer)**	**Procedure**
6:40	8:38	1:42	OR 25	Commercial HMO	Prostatectomy Radical/Laparoscopic Lymphadenectomy Bilateral
7:20	8:30	0:38	OR 21	Medicare	Cystoscopy TURP
8:55	11:40	2:06	OR 21	Medicare	Cystoscopy TURP
9:00	11:06	1:49	OR 25	Medicare	Prostatectomy Radical/Laparoscopic Lymphadenectomy Bilateral
11:38	13:50	1:52	OR 25	Medicare	Prostatectomy Radical/Laparoscopic Lymphadenectomy Bilateral
12:13	12:59	0:19	OR 21	M/Care Switch to HMO	Cystoscopy, Bladder Biopsies & Fulguration
13:30	14:35	0:33	OR 21	Medicare	Cystoscopy TURP
14:22	14:32	0:03	OR 25	Commercial HMO	Cystogram

14:50	16:33	1:02	OR 21	Medicare	Cystoscopy TURP
14:55	15:22	0:06	OR 25	Blue Cross	Cystogram
16:08	17:45	1:03	OR 21	Medicare	Cystoscopy TURP

190. Medicare paid (or was billed) for eight (8) out of the eleven (11) patients of Dr. Samadi undergoing surgery on March 5, 2014; the other three (3) were private commercial insurance.

191. Another example of the concurrent surgery practice is confirmed by Defendants' own urologic surgery and anesthesia databases for May 4, 2015, as illustrated below:

Anesthesia Start Time	**Anesthesia End Time**	**Dura-tion**	**OR**	**Patient Financial Class (Payer)**	**Procedure**
6:50	9:14	1:56	OR 25	Blue Cross	Prostatectomy Radical/Laparoscopic Lymphadenectomy Bilateral
9:00	10:30	0:55	OR 21	Commercial HMO	Cystoscopy TURP
9:35	12:30	2:22	OR 25	Blue Cross	Prostatectomy Radical/Laparoscopic Lymphadenectomy Bilateral
10:52	12:25	0:50	OR 21	Medicare	Cystoscopy TURP
12:55	15:30	1:59	OR 25	Commercial HMO	Prostatectomy Radical/Laparoscopic Lymphadenectomy Bilateral
15:50	18:25	2:02	OR 25	Medicare	Prostatectomy Radical/Laparoscopic Lymphadenectomy Bilateral
16:48	18:03	0:29	OR 24	Medicare	Ureteroscopy w/Homium YAG Laser

192. Specifically, on May 4, 2015, three (3) non-RALP endoscopic urologic surgeries were performed in O.R. 21 and 24 and four (4) RALPs were performed in O.R. 25. Two of the three non-RALP surgeries, performed by residents without proper supervision, were entirely or

completely encompassed by two of the RALP surgeries conducted by Dr. Samadi and one non-RALP surgery was mostly encompassed by one RALP.

193. The Lenox Hill / Northwell daily O.R. schedules for the urology department spanning the periods of August – October 2015 and February – March 2017 corroborate the existence of the concurrent surgery scheme perpetrated by Defendants Dr. Samadi, Lenox Hill and Northwell. The O.R. schedules demonstrate that Northwell/Lenox Hill managers and administrators must have been aware that Dr. Samadi was scheduling concurrent surgeries in O.R. 21 and O.R. 25 and could not possibly have been present in both places at the same time.

D. "Simultaneous Surgeries" Were Banned for Decades in the LHH Urology Department Pre-July 2013

194. During the period 2004 – June 2013, three attending urologists served in the position of chairman of the Lenox Hill urology department; it was department policy to ban concurrent or overlapping surgeries during this time period.

195. John A. Fracchia, M.D., served as chairman of urology at the hospital for twenty-five (25) years during the period 1983 – 2008; Dr. Fracchia remains affiliated as an attending urologist at LHH. Michael S. Brodherson, M.D. and R. Ernest Sosa, M.D., served as chairman or interim chairman of the LHH urology department between 2008 and 2013.

196. In July 2013, Dr. Samadi assumed the positions of chairman of the urology department and director of the urology residency program.

197. The urologic surgery databases corroborate a concurrent surgery ban during 2004 – 2013. The prior urology department chairmen refused to allow "simultaneous surgery," "concurrent surgery" or "double booking" practices by doctors in the LHH urology department. Such practices are entirely absent from the databases during the period 2004 – June 2013.

198. LHH urology department chairmen banned "simultaneous surgery" practices prior to July 2013 for the purpose of adherence to standards of patient safety, surgical practice, medical ethics, residency training, and lawful billing practices.

199. During the period that "simultaneous surgery" practices were banned in LHH's urology department, there was a robust, highly acclaimed, and fully ACGME-accredited urology residency program in which residents were properly trained in urologic surgery by assisting in and actually performing operative procedures under the constant direct supervision of the department's chairmen and attending urologists.

200. Since Dr. Samadi assumed the chairman and residency director positions in July 2013, the residents have been exploited by the Defendants – Dr. Samadi, Lenox Hill, and Northwell – to increase surgical volume, revenue, profits and physician compensation through performing unsupervised non-RALP surgeries in the course of the fraudulent "simultaneous surgery" scheme at the expense of the quality of the urology residency training.

201. The exploitation and compromise of the urology residency program for the purpose of advancing their fraud scheme to inflate surgical volume, revenue, profit, and physician compensation was undeniably acknowledged and even illustrated by the Defendants during the 2015 Lenox Hill Hospital urology residency graduation of Dr. Billy Cordon.

202. Documents indicate that during the 2015 urology residency graduation ceremony, Dr. Samadi presented graphs and statistics along with his own commentary boasting about the "increasing volume at Lenox Hill" for "overall all robotic cases at Lenox Hill" and "all urological cases over the past 5 years" and also voiced optimistic expectations that "[i]n the next 5 months we expect volume to persist, and surpass last year's numbers."

203. Documents also show, during the foregoing ceremony, Dr. Samadi also self-servingly commented that a "total of 865 prostatectomies were performed at LHH within the last 2 years!" More telling, during the foregoing ceremony, Dr. Samadi also enthusiastically exclaimed that an "*increase in overall volume means more: TURPs, lithotripsies, nephrectomies, penile implants" and that "[t]his achievement is made possible in large part by our residents: Billy Cordon, M.D., Yaniv Larish, M.D., Johnson Tsui, M.D., Shawn Mendonca, M.D. ...*".

204. The same information asserted by Dr. Samadi was displayed in a video presentation known as a "Prezi" display shown at the graduation ceremony.

205. As a result of the foregoing exploitation of the residents by Defendants Dr. Samadi, Lenox Hill and Northwell, proper urologic residency training has been compromised. Under Dr. Samadi's leadership as director, the accreditation of the Lenox Hill urology residency program was given a "warning" by the ACGME that was further downgraded to "probationary" status. (*See,* discussion, *infra.*)

E. False Claims for Unnecessary Anesthesia

206. Defendants David B. Samadi, M.D., David B. Samadi, M.D., P.C., Lenox Hill Hospital and Northwell Health Inc., fraudulently conspired to bill Medicare (and other government-funded health insurance programs) for general anesthesia services that were medically unjustifiable and excessively prolonged.

207. Dr. Samadi ordered general anesthesia for more than 1,000 surgeries in O.R. 21 during the period 2013 – 2016 so that the patients would be unaware that their surgery was being performed by an unsupervised urology resident and Dr. Samadi was not present in the operating room. The use of general anesthesia for the vast majority of the non-RALP surgeries on Dr. Samadi's patients in O.R. 21 is confirmed by the Northwell / LHH urologic surgery database, O.R. schedules, anesthesia records, and operative reports.

208. The use of general anesthesia for the surgeries performed by residents in O.R. 21 was not medically necessary or indicated under standards of proper urology practice since the surgical procedures are customarily and safely performed under spinal or epidural anesthesia with sedation.

209. The general anesthesia was also excessively prolonged for many of the surgeries in O.R. 21 since the resident performing the surgery had to await Dr. Samadi's temporary presence in the operating room to perform the mandated "timeout" so that the surgery by the resident could commence.

210. The practice of billing for unreasonable and unnecessary general anesthesia was not a remote occurrence in the course of the foregoing fraud scheme by the Defendants. The general anesthesia billing practices were commonplace and a direct outgrowth of the Defendants' "simultaneous surgery," "concurrent surgery," and "double booking" practices, which required (1) patients to be put under general anesthesia so that they would be unaware that their surgeon, Dr. Samadi, was not performing the operation as they had expected and under the circumstances serving as the basis of their consent to the operation; and (2) patients to be subject to surgical delays while under general anesthesia to await a mandatory "timeout" so the resident could begin the operation.

211. For this reason, virtually every claim by Defendants David B. Samadi, M.D., David B. Samadi, M.D., P.C., Lenox Hill Hospital and Northwell for Dr. Samadi's simultaneous / concurrent surgeries during 2013 – 2016 is not payable and constitutes a false claim since it includes charges for unnecessary and unreasonable general anesthesia.

F. False Claims Resulting From Defendants' Failure to Obtain Valid Informed Consent in Violation of Medicare Rules

212. Defendants David B. Samadi, M.D., David B. Samadi, M.D., P.C., Lenox Hill Hospital and Northwell Health, Inc., billed Medicare, and other public health care payers for surgeries, anesthesia services and related medical treatment that failed to conform to relevant Medicare rules.

213. The patients undergoing the urological surgeries in O.R. 21 were deceived by Dr. Samadi, who told them he would personally perform the planned surgery. Contrary to these misrepresentations, approximately 1,000 or more of Dr. Samadi's patients underwent surgery by unsupervised urology residents and were placed under general anesthesia without a proper informed consent.

214. From 2013 to 2016, Defendant Lenox Hill utilized various consent forms that are executed by patients before surgery; however, none informed patients that their surgeon would not be present during the surgery because the surgeon planned or intended to perform another surgery at the same time.

215. Moreover, Lenox Hill initially used consent forms that merely identified the attending (or teaching) surgeon performing the operation. Subsequently, the Lenox Hill's consent form was changed to include a space for inclusion of the specific identities of the "assistant" surgeons and/or "residents" involved in performing the surgery.

216. The operative report for Mr. Nadler's TURP identifies Johnson Tsui, M.D., as the "assistant" surgeon; however, the consent form signed by Nadler does not mention Dr. Tsui at all; it does not specify that Tsui was to be the "assistant" for the surgery, identify that Tsui was a resident, or state that Tsui was to perform the surgery.

217. This version of the consent form – presented to Relator Nadler in 2015 – fails to advise the patient that Dr. Samadi will be performing two surgeries at the same time and that a resident, Dr. Tsui in Nadler's case, will be performing surgery with or without the requisite supervision by Dr. Samadi.

218. Dr. Samadi, Lenox Hill, and Northwell actively sought to conceal their simultaneous / concurrent surgery scheme from Dr. Samadi's patients through the use of the informed consent forms. Dr. Samadi was specifically given a copy of the AUA's Code of Ethics and cautioned about adherence to the same on Feburary 7, 2014, in a letter sent to him by the American Urological Association.

219. The AUA letter related to an investigation into complaints against him from other physicians regarding extravagant and misleading statements in advertising.

220. In summary, Defendant Lenox Hill's consent forms, policies and practices fail to meet the criteria for an informed consent required by Medicare regulations, state law, medical ethics standards, and standards of proper urology practice; therefore, claims submitted by the Defendants for all the non-RALP surgeries by unsupervised urology residents in O.R. 21 constitute false claims.

G. Defendants' Medical Records Fail to Comply With Medicare Rules and Conceal False Claims

221. Defendants David B. Samadi, M.D., David B. Samadi, M.D., P.C., Lenox Hill Hospital and Northwell Health, Inc.. billed Medicare and other government payers for surgeries, anesthesia services and related medical treatment that involved the preparation of fraudulent medical records (*e.g.*, operative reports, anesthesia records, operative case records, etc.) that falsely indicated that Dr. Samadi had either performed the surgery, was present for "the critical or key portions of the surgery," and/or was present for the "entire viewing" portion of the

endoscopic / laparoscopic surgery for the operations in O.R. 21 performed by the unsupervised residents.

222. For example, the operative reports for the TURPs performed on Mr. Nadler and Mr. Markelson falsely indicated that the "surgeon" was Dr. Samadi, the "assistant" surgeons were Johnson Tsui, M.D., and Billy Cordon, M.D., and the reports were signed by Dr. Samadi; however, the evidence clearly demonstrates that Dr. Samadi was involved in performing a RALP in O.R. 25 during these two endoscopic urologic surgeries in O.R. 21.

223. Moreover, the operative reports for Mr. Nadler and Mr. Markelson surgeries do not state that Dr. Samadi was present in the O.R. for the "critical or key portions" of the surgery or the "entire viewing" portion of these endoscopic / laparascopic operations.

224. Finally, the operative reports for Mr. Nadler and Mr. Markelson fail to specify the identity of an available qualified teaching physician, *i.e.*, "backup attending surgeon," who was actually available to take over the surgery from the residents if necessary. None of the medical records for Mr. Nadler or Mr. Markelson surgeries maintained by LHH would have allowed a regulator to clearly infer that Dr. Samadi or the teaching physician was immediately available to return to either surgery in the event of complications.

225. None of the Lenox Hill medical records related to the "simultaneous" or "concurrent" non-RALP surgeries by the urology residents in O.R. 21 contain the foregoing requisite information and instead falsely indicate that Dr. Samadi was the surgeon performing the operative procedure. None of the Lenox Hill medical records related to the "simultaneous" or "concurrent" non-RALP surgeries by the urology residents in O.R. 21 accurately reflects who actually performed the surgery; instead the records are silent, misleading, untruthful or entirely false and/or contain significant omissions.

226. The medical records related to the "simultaneous," "concurrent" or "double booked" non-RALP surgeries by the urology residents in O.R. 21, particularly the operative reports, failed to comply with applicable regulations.

227. Accurate documentation of medical treatment pertaining to surgeries is a condition of Medicare reimbursement. Accurate documentation is critical as it helps ensure substantive compliance with Medicare regulations and allows detection of non-compliance with the law related to simultaneous / concurrent surgeries.

228. Defendants submitted false claims to the government for all the concurrent surgeries where the surgeon's records do not comply with these regulations.

229. In summary, virtually every claim submitted to Medicare by Defendants David B. Samadi, M.D., David B. Samadi, M.D., P.C., Lenox Hill Hospital and Northwell for the simultaneous/concurrent surgeries by unsupervised residents in O.R. 21 during 2013 – 2016 and to the present time is a false claim due to fraudulent medical records.

H. False Claims for "Upcoded" Bilateral Peripheral Lymph Node Dissections During RALPs

230. In some cases, Defendants "upcoded" billing during the robotic assisted laparoscopic prostatectomies (RALPs) performed by Dr. Samadi, prepared false medical records related to this upcoding, and fraudulently obtained the patients' informed consents for procedures that they knew would not be performed.

231. The Defendants prepared informed consents and operative reports falsely asserting that they would perform and did perform "bilateral peripheral lymph node dissections" when, in fact, Dr. Samadi did not resect the entire lymph node package on either side of the pelvis.

232. Instead, Dr. Samadi only resected one lymph node from the left and right. This procedure amounts to what is known as "lymph node sampling;" however, it serves no medical purpose

in the staging of prostate cancer and was done as a time-saving measure by Dr. Samadi so he could perform more RALPs in the course of an "operating day."

233. Moreover, the Defendants billed government payers, including Medicare for "bilateral peripheral lymph node dissections" that were never performed and performed "lymph node sampling" that served no medical purpose (*i.e.*, it was "medically unnecessary").

234. Defendants billed government payers for claims that were tainted by the foregoing violations of Medicare rules with regard to informed consent and falsified medical records.[42]

235. The Defendants submitted false claims for payment in contravention of the False Claims Act.[43] Defendants fraudulent "bilateral peripheral lymph node dissections" during the RALPs performed by Dr. Samadi endangered the health and welfare of his prostate cancer patients since it was never definitively established that the prostate cancer had not metastasized to the pelvic lymph nodes.

I. THE DEFENDANTS' STARK LAW AND ANTI-KICKBACK LAW VIOLATIONS

236. The Defendants also committed Stark law and Anti-Kickback Statute violations when they compensated Dr. Samadi in excess of fair market value and was based on the volume and value of business generated by Dr. Samadi for LHH.

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[42] The false claims for payment submitted by Defendants in relation to the simultaneous / concurrent surgery scheme and "upcoded" bilateral peripheral lymph node dissection during RALPs scheme included the CPT codes that define the specific operative procedures involved in each scheme for the purposes of determining the applicable payment or reimbursement rate. The CPT codes for the urologic surgeries involved in the Defendants' false claims submitted to Medicare are set forth in the "Available CPT Codes by Area and Type for Urology" issued by the ACGME. The Relators incorporate by reference the specific CPT codes for each of the surgical procedures performed on the Defendants' patients by unsupervised urology residents in O.R. 21 and for the "upcoded" bilateral peripheral lymph node dissection during RALPs performed by Dr. Samadi in O.R. 25 that constitute false claims under the False Claims Act.

[43] See, 42 C.F.R. 415.172(b).

237. The Defendants promoted the practice of Dr. Samadi in various ways through heavily funded and artificially enhanced internet advertising that directed patients exclusively to Dr. Samadi on their website.

238. The Defendants required that all emergency room patients and inpatients admitted to the hospital for treatment by other medical specialties in need of urology consults be referred or channeled to Dr. Samadi rather than distributed to other attending urologists through the traditional "on call" schedule used by hospitals.

239. The Defendants' website systematically excluded identification of all other attending urologists practicing at Lenox Hill (whether employees or voluntary attendings).

240. The Defendants also improperly prohibited other attending urologists from using the DaVinci robotic surgical system so as to restrict competition and create a monopoly for Dr. Samadi and themselves.

241. The Defendants foregoing conduct is in violation of the Stark Law (42 U.S.C. § 1395nn) and the Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)).

J. THE PROVISION OF GME WAS COMPROMISED

242. Defendants seriously compromised the Lenox Hill urology residency program in order to advance their fraud scheme to inflate the surgical volume, revenue, profit and physician compensation extracted from the department of urology.

243. Defendants' seriously compromised the supervision, training, and educational components of the Lenox Hill urology residency program to such an extreme extent that its accreditation status was incrementally downgraded by the ACGME to "accredited with warning" and then to "probationary" status.

244. Defendants further attempted to conceal their compromise of the urology residency program in an effort to maintain ACGME accreditation and approval and continue to receive Medicare GME funding.

245. Dr. Samadi's professional time, energy, and efforts were exclusively focused on performing RALPs at the expense of his responsibilities as urology residency program director.

246. Defendants exploited the residents labor to focus their time, efforts and energies on performing concurrent unsupervised non-RALP surgeries on Dr. Samadi's patients at the expense of their residency training and education.

247. The foregoing surgical activities were designed exclusively for the purpose of inflating surgical volume and revenue for the Defendants' benefit and devised to circumvent the requirement to properly supervise, train, and educate the residents.

248. In the process, Defendants' failed to meet their responsibilities and obligations to adequately supervise, train, and educate residents in accordance with ACGME requirements.[44] Defendants' foregoing compromise of the Lenox Hill urology residency program and failure to properly and adequately supervise, train, and educate residents in accordance with ACGME standards in order to facilitate their fraud scheme violated the conditions imposed by Medicare for the receipt of graduate medical education (GME) funding for Lenox Hill Hospital's residency programs. *See* 42 U.S.C. § 1395ww(h), 42 C.F.R. §§ 413.75, 413.76, 413.77, 412.105.

249. Defendants applied for and received funding from Medicare for GME costs related to the urology residence program at Lenox Hill Hospital, notwithstanding that the program did not

[44] *See* ACGME Program Requirements for Graduate Medical Education in Urology.

actually comply with the standards and requirements established by the relevant credentialing body, the ACGME.

250. In order to maintain the "approved" status of the ACGME and continue to receive federal funding from Medicare for direct and indirect GME costs associated with the program, Defendants falsified medical records and concealed material facts that would have revealed the fraudulent nature of the program and caused ACGME to withdraw program approval.

251. Defendants fraudulently committed the foregoing violations of Medicare regulations described in this Amended Complaint.

252. Defendants failed to properly and adequately train and educate urology residents in core "ACGME Competencies"[45] that included all medical, diagnostic and surgical procedures considered essential for the area of practice and failed to develop the residents' competence in the requisite "core techniques"[46]; this included an utter failure to train and educate residents in the performance of laparoscopic robotic urological surgeries – particularly robotic assisted laparoscopic prostatectomies.

253. Defendants systematically failed to properly and adequately meet ACGME requirements for supervision and accountability by intentionally evading compliance with the standard that residents and faculty members inform each patient of their respective roles in that patient's care when providing direct patient care.

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[45] See, ACGME Program Requirements for Graduate Medical Education in Urology, "ACGME Competencies," § IV.A.5.a.

[46] See, ACGME Program Requirements for Graduate Medical Education in Urology, "Core Techniques," § IV.A.5.a (IV.A.5.a).(2)(e)(i)-(vi)).

254. Defendants further concealed the corrupt nature of the urology residency program from the government in reporting GME costs on Lenox Hill's annual cost reports, and by seeking and accepting reimbursement of those costs from Medicare.

K. NORTHWELL, LENOX HILL HOSPITAL AND DR. SAMADI WERE WELL AWARE OF MEDICARE VIOLATIONS AND RESULTING FALSE CLAIMS ACT LIABILITY

255. Northwell's own compliance and ethics policy, in force since 2007, emphasizes the necessity for full compliance with all Medicare laws, regulations, rules and requirements and cautioned that a failure to comply with such rules had serious repercussions that included violations of the False Claims Act that could result in "significant civil and/or criminal penalties."

256. Northwell's compliance policy specifically applies to all of its facilities, including Lenox Hill, all employees and the medical staff, including Dr. Samadi.

257. Northwell's compliance policy specifically indicates that its workforce was educated about "Northwell Health policies, [and] the requirements, rights and remedies of Federal and state laws governing the submission of false claims."

258. Thus, Defendants were fully knowledgeable and aware that the foregoing actions violated Medicare regulations and yet Northwell Health and Lenox Hill authorized, approved, permitted, allowed, ratified, enabled, equipped, supported, assisted, encouraged, and promoted Dr. Samadi's fraudulent conduct at issue.

259. Northwell's compliance policy, in pertinent part, states the following:

> GENERAL STATEMENT OF PURPOSE
>
> It is the obligation of the Northwell Health and its affiliated entities ("Northwell Health") to prevent and detect any actions within the organization that are ***illegal, violative of federal and state health care programs (Medicare, Medicaid and other governmental payer programs), fraudulent*** or in violation of any applicable Northwell Health policy. .....

To this end, Northwell Health maintains a vigorous Compliance Program and strives to educate our work force regarding Northwell Health policies, the requirements, rights and remedies of Federal and state laws governing the submission of false claims, including the rights of employees to be protected as whistleblowers under such laws and the importance of submitting accurate claims and reports to federal and state governments.

POLICY

Northwell Health prohibits the violation of state and federal law, applicable Northwell Health policy and the knowing submission of a false claim for payment in relation to a federal or state-funded health care program. Such a submission violates the federal False Claims Act as well as various state laws, and may result in significant civil and/or criminal penalties. ....

SCOPE

This policy applies to all Northwell Health ***employees***, as well as ***medical staff***, volunteers, students, trainees, physician office staff, contractors, trustees and other persons performing work for or at Northwell Health; ....

260. Under the circumstances detailed above regarding corporate compliance policy, Defendants David B. Samadi, M.D., David B. Samadi, M.D., P.C., Lenox Hill Hospital and Northwell Health, Inc., knowingly, intentionally, and purposefully submitted claims for payment to Medicare containing false statements, misrepresentations, misleading assertions, omissions and "half-truths" that concealed violations of Medicare statutory, regulatory, and/or contractual requirements with respect to the foregoing medical services provided to covered patients.

261. Under the circumstances detailed above regarding knowledge and familiarity with Northwell's compliance and ethics policy, it is apparent that the Defendants knew, had reason to know, and even expected that the Medicare program would consistently refuse to pay such claims based on noncompliance with the applicable Medicare regulations if the claims submitted in relation to the simultaneous / concurrent surgeries by the unsupervised residents in O.R. 21 were truthful and accurate.

262. There have been no further notices or bulletins regarding the planned LHH "Overlapping Surgery" Policy published for hospital employees and staff, no distribution of such a policy to date, and no indication that Northwell executives will every approve such a policy that could restrict or limit simultaneous / concurrent surgery practices using unsupervised residents.

VI. DEFENDANTS' MEDICARE VIOLATIONS ARE MATERIAL

263. The expectation that critical surgeries are performed and/or supervised by fully credentialed and qualified physicians and that patients are fully informed as to all material elements of their surgeries is at the very core of the regulatory scheme. Violation of these requirements is material as that term is defined in the federal and state False Claims Acts and interpreted by the courts.

264. The centrality of 42 C.F.R. § 415.170 is underscored by its status as a condition of payment and by the legislative history. HHS enacted the current regulations to limit reimbursement "under the physician fee schedule" to situations where a teaching physician is "present for a key portion of the time during the performance of the service for which payment is sought," and "[i]n the case of a surgery or a dangerous or complex procedure," where the teaching physician is "present during all critical portions of the procedure" and "immediately available to furnish services during the entire service or procedure." Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 1996, 60 Fed. Reg. 63124, 63152 (HHS HCFA Dec. 8, 1995).

265. Responding to various public comments on the enactment of 42 C.F.R. §§ 415.170, 172, HHS explained the regulation clarified existing policy, particularly as to physical presence requirements, because "some teaching physicians are billing Medicare and receiving Part B payment for services even when the service is performed by an intern or resident outside the

presence of the teaching physicians and the teaching physician has minimal involvement, or no involvement, in the service." 60 Fed. Reg. at 63159.

266. In HHS's view, "a teaching physician should not receive a resource-based fee schedule amount when the physician has expended little or no resources with respect to the services." *Id.* HHS also stated:

> [W]e believe that, if we are to pay a fee to another physician who is medically responsible for the services the resident is furnishing to the beneficiary, it is entirely appropriate to require as a condition of payment that the supervising physician furnish a direct, personal physician service to the beneficiary. This is the basis for the payment of physician services under Medicare. If the resident has personally furnished the service to the beneficiary and the intermediary is paying the teaching hospital for Medicare's share of the services performed by the resident, we believe it is appropriate ***not*** to pay a full fee to a supervising physician who was not present when the service was furnished. Furthermore, the Medicare beneficiary is responsible for a 20 percent coinsurance amount for that physician's services as well as any deductible liability. We believe it is fully consistent with a resource-based fee schedule that the physician in whose name the service is billed furnishes a service to the ***beneficiary***.

Id. at 63162 (Emphasis added).

267. The government has consistently acted to punish and deter the conduct at issue by intervening in and litigating cases with substantively similar or identical regulatory violations to this case.

268. In a case against the University of Pittsburgh Medical Center, a *qui tam* relator alleged the Center violated 42 C.F.R. § 415.172 because teaching physicians billed and were paid for surgeries for which they were not physically present during the critical or key portions and did not supervise. The government intervened and settled these allegations.

269. The government also intervened in and settled a case against the Medical College of Wisconsin, alleging that billing surgeons were not present during "critical portions" of procedures or otherwise available to furnish services as required by regulation. There have been at least nine settlements by teaching hospitals involving similar issues in recent years. The

government also engaged in PATH audits, which resulted in 36 settlements with teaching hospitals, and many of these settlements involved overlapping surgeries and the regulatory violations at issue here.[47]

270. In a 1998 report to the House of Representatives' Ways and Means Committee on its ongoing PATH audits, the General Accounting Office ("GAO") expressly stated that HHS "does have a legal basis for applying the specific criteria used in the PATH initiative" and that the initiative "stem[med] from the continuing concern over Part B billings by physicians in a teaching setting."[48]

271. In its 1998 report, GAO also explained that HHS OIG's "first concern is whether teaching physicians who billed part B for services furnished by residents provided sufficient 'personal direction' in the delivery of the service." *Id.* at p. 6. Moreover,

> OIG considers that the requirement for sufficient personal direction is met if the physician was physically present while the service was delivered. If the medical records do not show evidence of the teaching physician's presence, the OIG considers the service to be part of the teaching physician's supervisory functions already paid under part A.

Id. Finally, OIG explained that "[w]ith the increased attention to health care fraud and abuse in recent years, the government may now invoke the penalties and damages prescribed in the False Claims Act for practices that in the past might have been dealt with by seeking repayment." *Id.* at p. 7.

272. CMS, likewise, was not content to leave limitations on concurrent surgeries set forth in 42 C.F.R. § 415.170 and 42 C.F.R. § 415.172(a) open to interpretation by Lenox Hill and other

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[47] HHS OIG reported that these 36 teaching hospitals settled False Claims Act or other similar cases related to these audits and investigations between 1995 and 2004, for amounts in excess of $225 million.

[48] *See* GAO Report to the Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives, "Medicare Concerns With Physicians at Teaching Hospitals (PATH) Audits," July 1998 at pp. 3, 6; found at https://www.gao.gov/archive/1998/he98174.pdf.

hospitals or providers. Rather, CMS provided extensive guidance on the responsibilities of teaching physicians, explaining what surgical practices are and are not permissible for overlapping surgeries. *See supra* ¶¶ 10-11, 68-83. Defendants failed to adhere to this guidance.

273. CMS has emphasized the materiality of appropriate record-keeping by providing detailed guidance on documentation (*supra* ¶¶ 68-69, 80-82, 97-99). Accurate documentation is critical as it helps ensure substantive compliance and allow detection of non-compliance with the law when conducting overlapping surgeries. The regulatory history also underscores the materiality of accurate and adequate documentation. In promulgating 42 C.F.R. § 415.172, CMS rejected comments arguing documentation requirements would be too onerous, explaining that "[t]he policy we are adopting cannot be enforced without some documentation of the presence of the teaching physician during procedures." 60 Fed. Reg. 63124 at p. 44 (December 8, 1995).

274. Similarly, CMS adopted interpretive guidelines setting forth the contours of informed consent and codes of medical ethics have long warned that concurrent surgeries, in the manner conducted by Defendants, are unethical. *Supra* ¶¶ 88-93.

275. Finally, HHS Guidance Document entitled "Items and Services Not Covered Under Medicare" underscores the materiality of Lenox Hill's violations.[49]

276. Moreover, charging for services that were not rendered or "upcoding" – such as performing a "lymph node sampling" but charging for a "peripheral lymph node dissection" – is also material to the government's decision to pay. The U.S. Department of Justice (DOJ) has prosecuted and reached significant settlements involving similar upcoding schemes. For

[49] Medicare Learning Network Booklet, "Items and Services Not Covered Under Medicare," August 2018 at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Items-and-Services-Not-Covered-Under-Medicare-Booklet-ICN906765.pdf.

example, Nextcare, Inc. paid $10 million to resolve claims brought by several states and the federal government alleging that the company billed for unnecessary allergy, flu and respiratory panel testing and inflated urgent care medical services in 2012.[50]

277. Likewise, DOJ has consistently prosecuted False Claims Act cases where providers submit claims for treatments or procedures that not are not medically necessary (such as the lymph node sampling done by Dr. Samadi) and, therefore, such false claim are also material. For example, in 2003, Tenet Healthcare paid $54 million to settle claims that its doctors in California "conducted unnecessary heart procedures."[51]

278. No federal or state government payer has paid claims with actual knowledge that Defendants violated governing regulations and conditions of payment or participation. As the First Circuit has stated, "mere awareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance." *U.S. ex rel. Escobar v. Universal Health Servs.*, 842 F.3d 103 (1st Cir. 2016). As detailed herein, Defendants have acted to conceal the nature of their concurrent surgeries and other violations from regulators, patients, and the public at large.

VII. COUNTS

FIRST COUNT
U.S. FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(1)(A)
AGAINST ALL DEFENDANTS

279. All of the preceding allegations are incorporated by reference in this paragraph.

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[50] U.S. Department of Justice Press Release, July 2, 2012, Arizona-based Nextcare Inc. to Pay US $10 Million to Resolve False Claims Act Allegations, at https://www.justice.gov/opa/pr/arizona-basednextcare-inc-pay-us-l0-million-resolve-false-claims-act-allegations (last visited April 27, 2018).

[51] Eichenwald, K., Tenet Healthcare Paying $54 Million in Fraud Settlement, August 7, 2003, New York Times at https://www.nytimes.com/2003/08/07/business/tenet-healthcare-paying-54-million-in-fraud-settlement.html (last visited March 5, 2019).

280. This is a claim for treble damages and civil penalties under 31 U.S.C. § 3729(a)(1)(A), *i.e.*, the False Claims Act.

281. As a result of the foregoing scheme, conduct, acts, transactions, occurrences and regulatory violations, the Defendants knowingly presented to Medicare and other government-funded health insurance programs false claims (1) for simultaneous / concurrent surgeries that did not comply with Medicare supervision regulations; (2) for simultaneous / concurrent surgeries that involved unnecessary anesthesia services; (3) for simultaneous / concurrent surgeries that lacked a valid informed consent from the patient; (4) for simultaneous / concurrent surgeries that were not properly documented in the medical records; (5) for surgeries that were "upcoded bilateral peripheral lymph node dissections" during RALPs that were falsely documented in the medical records; (6) tainted by Stark Law and Anti-Kickback Statute violations; and (7) tainted by Defendants' compromise of the supervision, training and educational components of the urologic residency program in violation of the conditions for GME funding for Lenox Hill Hospital and attempted concealment of the same.

282. The United States, unaware of the falsity or fraudulent nature of the claims submitted by the Defendants, paid for claims that would not have otherwise been allowed.

283. It was foreseeable and, in fact, Defendants' intended result that federal monies would be used to pay, in whole or in part, for false or fraudulent claims they submitted or caused to be submitted to Medicare and other government-funded health insurance programs. At all relevant times, each Defendant acted with the requisite scienter.

284. By reason of these payments, the United States has been damaged and continues to be damaged in a substantial amount.

SECOND COUNT
U.S. FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(1)(B)
AGAINST ALL DEFENDANTS

285. All of the preceding allegations are incorporated by reference in this paragraph.

286. This is a claim for treble damages and civil penalties under 31 U.S.C. § 3729(a)(1)(B), *i.e.*, the False Claims Act.

287. As a result of the foregoing scheme, conduct, acts, transactions, occurrences and regulatory violations, the Defendants knowingly made or used false records and/or statements that caused false claims to be submitted to Medicare and other government-funded health insurance programs.

288. The United States, unaware of the falsity or fraudulent nature of the claims submitted by the Defendants, paid for claims that would not have otherwise been allowed.

289. It was foreseeable and, in fact, Defendants' intended result that federal monies would be used to pay, in whole or in part, for false or fraudulent claims they submitted or caused to be submitted to Medicare and other government-funded health insurance programs. At all relevant times, each Defendant acted with the requisite scienter.

290. By reason of these payments, the United States has been damaged and continues to be damaged in a substantial amount.

THIRD COUNT
U.S. FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(1)(C)
AGAINST ALL DEFENDANTS

291. All of the preceding allegations are incorporated by reference in this paragraph.

292. This is a claim for treble damages and civil penalties under 31 U.S.C. § 3729(a)(1)(C), *i.e.*, the False Claims Act.

293. Defendants entered into a conspiracy or conspiracies to defraud the United States through the foregoing scheme, conduct, acts, transactions, occurrences and regulatory violations to knowingly submit false claims (1) for simultaneous / concurrent surgeries that did not comply with Medicare supervision regulations; (2) for simultaneous / concurrent surgeries that involved unnecessary anesthesia services; (3) for simultaneous / concurrent surgeries that lacked a valid informed consent from the patient; (4) for simultaneous / concurrent surgeries that were not properly documented in the medical records; (5) for surgeries that were "upcoded bilateral peripheral lymph node dissections" during RALPs that were falsely documented in the medical records; (6) tainted by Stark Law and Anti-Kickback Statute violations; and (7) tainted by Defendants' compromise of the supervision, training and educational components of the urologic residency program in violation of the conditions for GME funding for Lenox Hill Hospital and attempted concealment of the same.

294. The United States, unaware of the falsity or fraudulent nature of the claims submitted by the Defendants, paid for claims that would not have otherwise been allowed.

295. It was foreseeable and, in fact, Defendants' intended result that federal monies would be used to pay, in whole or in part, for false or fraudulent claims they submitted or caused to be submitted to Medicare and other government-funded health insurance programs. At all relevant times, each Defendant acted with the requisite scienter.

296. By reason of these payments, the United States has been damaged and continues to be damaged in a substantial amount.

FOURTH COUNT
U.S. FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(1)(G)
AGAINST ALL DEFENDANTS

297. All of the preceding allegations are incorporated by reference in this paragraph.

298. This is a claim for treble damages and civil penalties under 31 U.S.C. § 3729(a)(1)(G), *i.e.*, the False Claims Act.

299. As a result of the foregoing fraudulent scheme, conduct, acts, transactions, occurrences and regulatory violations, the Defendants knowingly made, used and/or caused the use of false records and/or statements that are material to an obligation to pay or transmit money by the United States.

300. The United States, unaware of the falsity or fraudulent nature of the claims submitted by the Defendants, paid for claims that would not have otherwise been allowed.

301. At all relevant times, each Defendant acted with the requisite scienter in that they knew that they had been overpaid by Medicare and other government-funded health insurance programs but did not take the required and appropriate steps to satisfy the obligation owed to these payers, to refund or return such overpayments, or to inform these payers of the overbilling, and instead continued to retain the same, and to overbill these programs.

302. Because Defendants have failed to reimburse the federal government for sums they unlawfully received as a result of the foregoing fraudulent scheme, conduct, acts, transactions, occurrences and regulatory violations, the United States has been damaged and continues to be damaged in a substantial amount.

VIII. PRAYER FOR RELIEF

WHEREFORE, for each of these false claims, the *qui tam* Relators request the following relief from each of the Defendants, jointly and severally:

1) Three times the amount of damages that the federal government has sustained as a result of the acts of the Defendants on each count;

2) A civil penalty of not less than $5,500.00 and not more than $11,000.00[52] for each violation of 31 U.S.C. § 3729 and/or for the maximum amount set by law or final rule;

3) An award to the Relators of the maximum "relator's share" allowed pursuant to 31 U.S.C. § 3730(d);

4) An award to the Relators of reasonable attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d));

5) Interest; and

6) Such other and further relief as the Court deems to be just and proper.

IX. JURY DEMAND

303. Relators demand trial by jury of all issues presented in this action that are triable as of right by a jury pursuant to Fed. R. Civ. P. 38 (a).

Dated: New York, NY
May 31, 2019

Respectfully submitted,

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[52] As adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461; *see also* 84 F.R. 66, at 13520 (DOJ Apr. 5, 2019) (explaining 2019 amounts are unchanged from 2016 amounts); 81 F.R. 126, at 42491 (DOJ June 30, 2016) (setting forth 2016 increases).

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Attorneys for Relators
GEORGE MARKELSON, as Executor
of the Estate of STEPHEN
MARKELSON, Deceased, PETER
NADLER and LORRAINE WATERS

*Will file *pro hac vice* motions shortly

CERTIFICATE OF SERVICE

I hereby certify that a copy of Plaintiff-Relators' Amended Complaint was served upon the following persons, this ____day of _____, 2019 via the means indicated below.

_____
Joseph Lanni

VIA FIRST CLASS MAIL
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